MISOPROSTOL WITH FOLEYS CATHETER

VERSUS

MISOPROSTOL ALONE

FOR INDUCTION OF LABOR IN TERM PRIMIGRAVIDAS

A PROSPECTIVE RANDOMIZED CONTROL TRIAL

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE RULES AND REGULATIONS FOR THE MS BRANCH (OBSTETRICS AND GYNAECOLOGY) EXAMINATION OF THE TAMIL NADU DR. M. G. R. MEDICAL UNIVERSITY TO BE HELD IN APRIL 2017

CERTIFICATE

This is to certify that this dissertation entitled "MISOPROSTOL WITH FOLEYS CATHETER VERSUS MISOPROSTOL ALONE FOR INDUCTION OF LABOUR IN TERM PRIMIGRAVIDAS – A PROSPECTIVE RANDOMIZED CONTROL TRIAL" is a bonafied work done by Dr. Neeraj Kulkarni in partial fulfillment of the requirement for the MS branch (Obstetrics and Gynaecology) examination of the Tamil Nadu Dr M.G.R Medical University, Chennai to be held in April 2017

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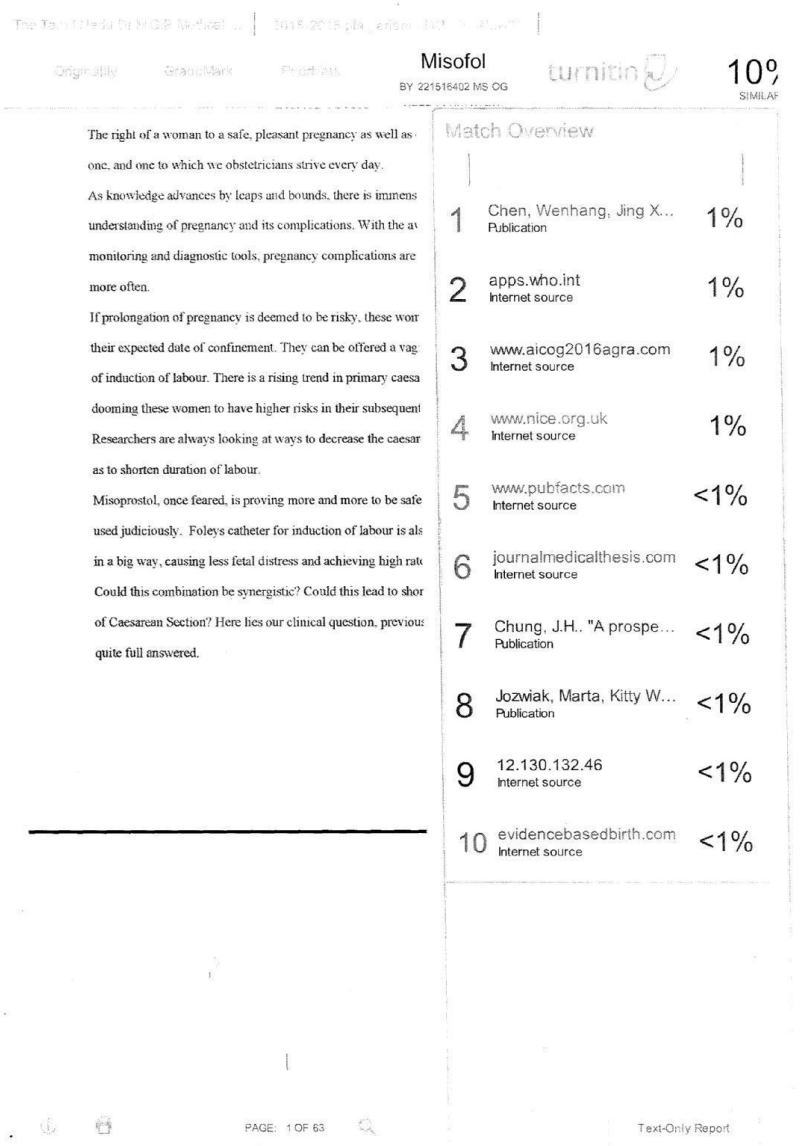

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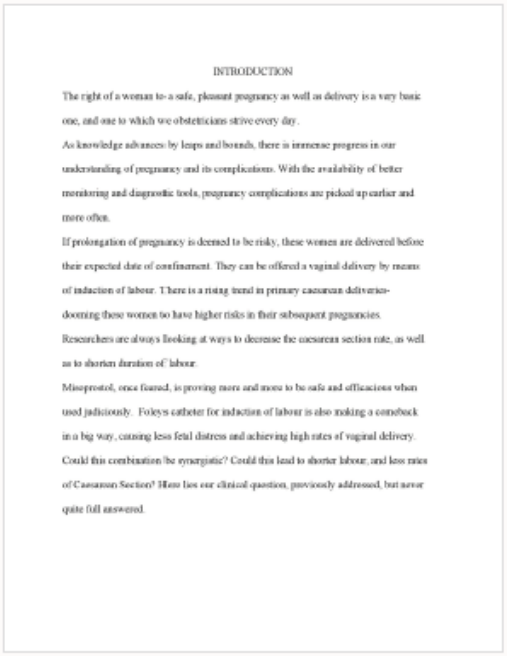

INTRODUCTION

The right of a woman to- a safe, pleasant pregnancy as well as delivery is a very basic one, and one to which we obstetricians strive every day.

As knowledge advances by leaps and bounds, there is immense progress in our understanding of pregnancy and its complications. With the availability of better monitoring and diagnostic tools, pregnancy complications are picked up earlier and more often.

If prolongation of pregnancy is deemed to be risky, these women are delivered before their expected date of confinement. They can be offered a vaginal delivery by means of induction of labour. There is a rising trend in primary caesarean deliveries- dooming these women to have higher risks in their subsequent pregnancies.

Researchers are always looking at ways to decrease the caesarean section rate, as well as to shorten duration of labour.

Misoprostol, once feared, is proving more and more to be safe and efficacious when used judiciously. Foleys catheter for induction of labour is also making a comeback in a big way, causing less fetal distress and achieving high rates of vaginal delivery.

Could this combination be synergistic? Could this lead to shorter labour, and less rates of Caesarean Section? Here lies our clinical question, previously addressed, but never quite full answered.

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September 12, 2016

Dr. Neeraj Kulkarni
PG Registrar,
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Sub: **Fluid Research Grant NEW PROPOSAL:**
Misoprostol with Foleys catheter versus Misoprostol alone for induction of labor in term primigravidas - a prospective randomized control trial.
Dr. Neeraj Kulkarni (Employment Number: 33060), PG Registrar, Obstetrics & Gynaecology unit 3, Dr. Jessie Lionel, Professor & HOU , Obstetrics & Gynaecology unit 3

Ref: IRB Min No: 9634 [INTERVEN] dated 23.09.2015

Dear Dr. Neeraj Kulkarni,

The Institutional Review Board (Silver, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Misoprostol with Foleys catheter versus Misoprostol alone for induction of labor in term primigravidas - a prospective randomized control trial" on September 23rd 2015.

The Committee raised the following documents

1. IRB Application format
2. Patient Information Sheet and Informed Consent Form (English, Tamil, Hindi)
3. Cvs of Drs. . Neeraj Kulkarni, . Jessie Lionel
4. No. of documents 1 - 3

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Name	Qualification	Designation	Affiliation
Dr. B. Antonisamy	MSc, PhD, FSMS, FRSS	Professor, Biostatistics, Secretary (Research Committee), IRB, CMC, Vellore	Internal, Statistician
Dr. Prasanna Samuel	MSc, PhD	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
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We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any **adverse events** occurring in the course of the project, any **amendments in the protocol and the patient information / informed consent**. On completion of the study you are expected to submit a copy of the **final report**. Respective forms can be downloaded from the following link:

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Fluid Grant Allocation:

A sum of 41,114/- INR (Rupees Forty one Thousand one hundred and fourteen only) will be granted for 1 year and out of which a maximum of Rs.5000/- can be spent for stationery, printing, Xeroxing and computer charges(If computers used are within the institution)

Yours sincerely

Dr. Antonisamy
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Christian Medical College, Vellore

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Dear Dr. Neeraj Kulkarni,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Antonisamy
Secretary (Research Committee)
Institutional Review Board

Ethics Committee Silver, Office of Research, I Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
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My Dear wife Dr. Deepti, who indeed makes all this worth the while.

Above all, to Him who is able to do far more abundantly than all we can ask or imagine, to Him be all glory forever and ever.

CONTENTS

INTRODUCTION

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AIMS AND OBJECTIVES OF THE STUDY

Aim:

To compare the efficacy of Foleys catheter with Misoprostol (combination) versus Misoprostol alone for the prupose of induction of labour.

Objectives:

To determine whether use of Foleys in combination with Misoprostol, as opposed to

Misoprostol alone, for induction of labour will lead to

i. Decreased induction to delivery interval
ii. Higher probability of achieving vaginal delivery
iii. Lower incidence of Caesarean section
iv. Affect the rates of meconium stained liqour
v. Lower rates of hyperstimulation
vi. Affect incidence of chorioamnionitis/ endomyometritis
vii. Lower rates of atonic post partum haemorrhage
viii. Affect neonatal morbidity

REVIEW OF LITERATURE

Literature Review Structure

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Indications

Contraindications

Techniques of Induction of Labour

Predicting success of Induction of Labour

Risks of Induction of Labour

Preinduction cervical ripening: Methods

- Pharmacological: Prostaglandin E2, Prostaglandin E1, Prostaglandin F2Alpha, Nitric Oxide Donors, Oxytocin
- Mechanical Methods: Transcervical catheter, Hygroscopic Cervical Dilators, Membrane stripping

Failed induction

Misoprostol and Foleys versus Misoprostol alone – Current Knowledge

Introduction

Induction of labour is the stimulation of uterine contractions before the spontaneous onset of labour, in the presence or absence of membranes (1).

Induction of labour is indicated in cases where continuation of pregnancy poses more risk than benefit to the mother or/and fetus. Some examples of these situations are, rupture of membranes before the start of uterine contractions, oligohydramnios, gestational hypertension, intrauterine growth restriction, maternal indications such as diabetes mellitus/ chronic hypertension (2). Easy availability of ripening agents, and patient request also play an important role in increasing rates of induction of labour (3). Electively inducing labour for convenience to the obstetricians schedule has also been recognized as a major contributing factor (4).

Induction of labour at term: Continuation of pregnancy beyond 42 weeks is associated with complications to the mother and the fetus. A Cochrane review studied 22 trials that induced labour between 37 and 42 weeks of gestation, compared to waiting for spontaneous labour (5). It was found that earlier induction resulted in fewer perinatal deaths, less meconium aspiration and fewer caesareans than the policy of waiting. A systematic review by Caughey et al which included 11 randomised control trials suggested that elective induction of labour after 41 weeks resulted in a decreased risk for caesarean delivery and meconium stained amniotic fluid (6).

Prevalence of Induction of Labour: Induction rates seem to have increased in the last decade. A study done in the US showed that the rate of induction of labour has increased nationwide from 9.5% to 19.4% between the years 1990 and 1998 (3).

Increased rates of medically indicated inductions did not contribute to this rise as much as marginally indicated, or elective inductions. These contribute to at least half of all inductions, and induction of labour in nulliparas with an unfavourable cervix results in rising rates of caesarean sections (7).

A national survey was done in the USA by Childhood Connection to ascertain the experiences of women during pregnancy and labour (8) . 2400 women completed a detailed online questionnaire. 41% of these women underwent induction of labour. The most common rationale given to these mothers for inducing labour was that the baby was overdue (18%), and a maternal health problem that required a quick delivery (18%).

In Christian Medical College, Vellore, incidence of induction of labour whenever indicated, is about 15- 20%. The rate of primary LSCS is about 18-24%, failed induction accounting for 6-10% of cases.

Why is Induction of labour so important?

The increase in LSCS rate has been a global phenomenon. From the year 1970 to 2010, the rate of caesareans in the USA has risen from 4.5% of all deliveries to 32.8% (9). LSCS rate in England is 21.5 % (10), and in Latin American countries around 40 % (11). World Health Organization advises that Cesarean Section (CS) rates should not be more than 15%. There is evidence that CS rates above 15% are not associated with additional reduction in maternal and neonatal mortality and morbidity (12).

To make the number of elective/ marginally indicated inductions safer, it is imperative to find means of induction of labour that have the greatest success rate.
And such safe methods of induction of labour will lower caesarean deliveries and its added complications.

Methods of Induction of Labour: Many women in whom induction of labour is indicated have an unfavourable cervix. Thus, much research has dealt with ways to 'ripen' the cervix before stimulating uterine contractions.
These methods are:

- Pharmacological Methods: Prostaglandin E2, Prostaglandin E1,Prostaglandin F2alpha, Nitric Oxide Donors
- Mechanical Methods: Transcervical catheter, Hygroscopic Cervical Dilators, Stripping of membranes

These methods alone have been extensively studied, with evidence supporting their use.
Prostaglandin E1 acts by modifying collagen and alters concentration of glycosaminoglycans in the cervix. It has been found to shorten induction to delivery interval, decrease the need for oxytocin administration, and achieve more vaginal deliveries within 24 hours as compared to other prostaglandins (13).
Intracervical placement of Foleys catheter for the purpose of mechanical ripening of the cervix was first described in 1967 (14). It acts by local dilatation of the cervix, and also by stimulating the release of endogenous prostaglandins and oxytocin (15).

The prospect of combining mechanical and pharmacological methods is a challenging one, and has not been studied in systematic randomized control trials.

In a meta-analysis done by Chen et al. (16), eight trials were analysed – a total of 1153 patients. These studies sought to compare Foleys plus Misoprostol versus Misoprostol alone for ripening of the cervix. The group that used both methods of induction together had decreased time from induction to delivery intervals (mean difference –2.36 hours, 95% confidence interval [CI] –4.07 to –0.66; $P = 0.007$). However, the risk of chorioamnionitis was found to be higher in the combination group (risk ratio [RR]2.07, 95% CI 1.04–4.13; $P = 0.04$). Risk of tachysystole and non reassuring fetal status was decreased (RR 0.58, 95% CI 0.38–0.91; $P = 0.02$). The caesarean rates did not differ in the two groups (p=0.77).

The authors concluded that the combined use of these methods lead to a decreased induction to delivery interval, less tachsystole and fetal heart rate changes but an increased rate of chorioamnionitis.

However many of these trials were underpowered. None of them clearly state the difference in improvement in caesarean section rate.

This trial is planned to clearly elucidate if there are any, benefits of combining Foleys and Misoprostol versus Misoprostol alone for ripening of the cervix for induction of labour.

Induction of Labour

Induction of labour refers to the artificial stimulation of uterine contractions to cause delivery before labour spontaneously sets in. Closed, uneffaced cervix leads to prolonged latent phase and labour itself. Cervical ripening is the process by which the

cervix is softened and effaced leading to shorter labour. The cervix can be ripened by pharmacological as well as mechanical methods.

Guidelines for induction of labour

National Institute for Health Care and Excellence (NICE) guidelines (July 2008)(17)
Women must be counseled that most pregnant women will experience spontaneous labour by 42 weeks. At 38 weeks, during antenatal check up, women should be informed about risks associated with post term pregnancies, and the options that are available.

This counseling should cover

- Sweeping of membranes
- Inducing labour between 41+0 and 42+0 weeks
- expectant management.

When offering induction of labour, key counseling points are

- Why induction is necessary
- The method of induction planned
- Pain relief and support available
- Alternate options if she is not willing for induction of labour
- Risks and benefits of the proposed methods of induction
- That induction is not always successful

Healthcare workers must remember to

- Allow the woman and her partner to come to their own decision
- Invite questions from the patient and her partner
- Support the patient whatever may be her decision

Recommended methods for induction of labour

- Sweeping of membranes
- Pharmacological methods
    - — Prostaglandin E2: Is the preferred method
    - — Misoprostol (Prostaglandin E1) should only be used in cases of intrauterine death.

Mechanical Methods: Balloon catheters are not routinely recommended for induction of labour.

The Society of Obstetricians and Gynaecologists of Canada (SOGC) Guidelines (18)

- Prostaglandins (vaginal and cervical), are effective in the use of ripening the cervix and inducing labour when cervix is unfavourable.

- Vaginal prostaglandins are preferred as they are able to achieve more timely vaginal deliveries than intra-cervical prostaglandins.

- Indication for induction of labour should be documented. Discussion should comprise the method for induction, the reason for induction and risks involved. These should cover the possibility of failure to commence labour, and well as increased risk for Caesarean delivery.

- When induction of labour is unsuccessful, the method and indication for induction must be re-evaluated.

- Induction should not be undertaken solely for provider/ patient preferences.

- Health care providers should use the Bishops score to assess the cervix favourability- both to determine method of induction, as well to predict the likelihood of success. Bishops score must be carefully documented.

- Women between the gestational ages of 41+0 and 42+0 should be offered induction of labour. This may decrease meconium aspiration syndrome as well as perinatal mortality rates without increasing the caesarean section rates.

- Those patients that decline induction at >41 weeks should be closely monitored twice a week for fetal well being.

- Use of Foleys catheter intracervically for induction is acceptable, both as an outpatient procedure, as well as for induction of labour for vaginal birth after Caesarean section.

- Prostaglandins should not be used for vaginal births after Caesarean section as this increases the risk of scar rupture.

- Misoprostol can be both safe and effective for induction when membranes are intact, and on an inpatient basis.

Indications for Induction of Labour

- Post term pregnancies
- Prelabour rupture of membranes
- Preterm prelabour rupture of membranes
- Abruptio Placenta
- Intrauterine fetal demise
- Oligohydramnios
- Preclampsia, Eclampsia, HELLP
- Cholestasis of pregnancy
- Fetal growth Restriction
- Twin gestation
- Maternal Diabetes

Marginally indicated induction/ Elective induction of labour at term:

Elective or "social" induction is associated with many concerns such as increased risk of Caesarean sections in the latent phase, increased duration of labour and neonatal morbidity if done before 39 weeks (19) . The potential benefits of induction of labour at term include reduced rates of macrosomia and its complications, rates of still births and passage of meconium (but not rates of meconium aspiration) (20,21) . The risk of sudden, unattended labour is reduced in women who have a history of precipitate labour. Elective labour also decreases the chances of disrupting the patients/providers work and home responsibilities. However, most experts agree that elective induction should not be done before 39 weeks of gestation. ACOG cautions that rates of morbidity and mortality are much greater among infants and neonates that delivered

during early term compared with those that delivered between 39 and 40 weeks of gestation (22) . However they also stress that this should not dissuade health care professionals from carrying out indicated early term inductions, and benefits of early induction versus risks of prolonging pregnancy should be carefully weighed before coming to a decision.

There is no consensus however on elective induction of labour from 39 to 41 weeks. A randomized control trial done showed no additional risk of caesarean, or adverse maternal/ neonatal short term outcomes with induction at this gestation(23).

Contraindictions to Induction of Labour: These comprise conditions that preclude labour/ vaginal delivery.

Some examples are-

- Prior Uterine Incision in the upper segment.
- Contracted pelvis
- Placenta praevia – major degree
- Active genital herpes
- Cervical cancer
- Fetal macrosomia
- Non reassuring fetal status
- Malpresentation
- Severe hydrocephalus

Techniques for induction of labour

For decades, oxytocin has been used to augment and induce labour. Other drugs that are newer to armamentarium are Prostaglandins E1 and E2. Mechanical methods are available, such as intracervical balloon dilators, hygroscopic dilators, amniotomy, stripping of membranes. ACOG 2012 recommends that each obstetrician/ Hospital have their own written guidelines and protocols for the induction and augmentation of labour.

Predicting successful induction of labour

Prediction of successful induction of labour depends on several factors such as :

- Maternal factors – Age, parity, status of membranes, Bishops score, gestational age, maternal body mass index, maternal height.
- Fetal factors- estimated fetal weight
- Placental factors- Presence/ absence of placental insufficiency

Studies have shown that rates of live vaginal births were found to increase as gestational age increases. Feghali et al in 2015 studied women being induced for medical reasons at <37 weeks of gestational age. They divided the patients into groups according to gestational age (group A- 24-27+6 weeks; B- 28-30+6 weeks; C- 31-33+6 weeks; and D- 34-36+6 weeks). They found that as one progressed from group A to group D, incidences of vaginal live births increased from 35% (in group A) to 75% (in group D) (24). In the same study, when looking at labour curves for nulliparous women, it was found that as gestational age decreases, the overall duration of labour increases. However, the duration of the active phase seemed to remain the same across gestational age.

Multiparous women with favourable cervix at the start of induction had higher chances of achieving vaginal delivery. The Bishops score in particular is a useful tool for predicting vaginal delivery, and should routinely be used to assess favourability of the cervix prior to induction of labour.

Modified Bishops score(25)

Cervical feature	**Modified Bishop score**			
	0	**1**	**2**	**3**
Dilation (cm)	< 1	1–2	2–4	> 4
Length of cervix (cm)	> 4	2–4	1–2	< 1
Station (relative to ischial spines)	−3	−2	−1/0	+1/+2
Consistency	Firm	Average	Soft	–
Position	Posterior	Mid/anterior	–	–

Bishops Score comprises of 5 parts: effacement or length of cervix , dilatation of cervix, its consistency and position, the station of the presenting part in relation to the ischial spines. This score was originally described in multiparous women .

Vrouenraets et al., 2005 have shown a good correlation with a favourable Bishops score prior to induction and rates of successful induction of labour (26).

A Bishops score of >8 is predictive of successful vaginal birth. Systematic reviews of randomized controlled trial have shown that the Bishops score seems to be the most superior tool for predicting successful induction. Dilatation seems to be the most important component of Bishops score (27).

Other tools which can be used to assess favorability of the cervix are Fields system and Burnett, Caldor, and Friedman modifications of the Bishop system.

Risks of Induction of Labour

Inducing labour is not without risk, and these should be discussed with the patient and documented before the process is initiated.

The risks can be divided into

- Maternal: Higher rates of Caesarean section, chorioamnionitis, rupture of uterine scar and uterine atony post delivery leading to post partum haemorrhage.

- Fetal: Fetal distress, neonatal infection

Caesarean Section delivery rate

Caesarean delivery rate is widely believed to be increased in nulliparas undergoing induction of labour. Maslow and Sweeny, 2000 have reported the risk being two to three fold higher in this population (28) . As stated before, these rates seem to be inversely related to the Bishops score at the beginning of induction. In fact, Mercer et al have found that in nulliparous women with an unfavourable cervix, preinduction ripening doesn't show much benefit in decreasing caesarean section rates (29) . The station of the fetal head may also be an important contributing factor. Shin et al found that nulliparas more than 41 weeks of gestation with an unengaged vertex had a 12 fold increase risk of caesarean delivery than those with an engaged vertex(30) .

Of late, there have been arguments against the premise that women undergoing an elective induction of labour have higher rates of caesarean deliveries. A Cochrane review published in 2012 was undertaken to address the benefits/ harms of labour induction at term/ post-term compared to inducing labour later or awaiting spontaneous labour (31) . In 21 trials, comprising 8749 women, they found that there were fewer caesarean deliveries for the induction of labour arms compared to a policy of awaiting spontaneous labour (RR 0.89, 95% CI 0.81 to 0.97).

Saconne et al (32) undertook a meta-analysis which was published in 2015 to evaluate the potential risk of caesarean delivery, and also maternal /perinatal morbidity in induction of labour for uncomplicated term singleton pregnancies. They studied randomized control trials which included uncomplicated singleton pregnancies at full term gestation (39+0 weeks to 40+6 weeks), with intact membranes, randomized to induction of labour versus expectant management. Primary outcome studied was incidence of caesarean deliveries. They analysed 5 RCTs comprising 844 women. The authors found that Caesarean section incidence in those that underwent induction of labour were similar as compared to controls (9.7% vs 7.5%; RR, 1.25; 95% CI, 0.75-2.08).

Secondary analysis of the DIGITAT (fetal growth restriction) and HYPITAT (hypertension in pregnancy) trials was done. It was found that in women with a Bishops score of a median of 3 who were induced at term, there was no increase in incidence of caesarean delivery as compared to expectant management. Approximately 85% of patients in both arms achieved a vaginal delivery (33) . Thus caesarean rates at term may not be dependent on Bishops score at inuduction.

Chorioamnionitis

Amniotomy is associated with a higher incidence of chorioamnionitis as compared to other methods of induction of labour (ACOG, 2013a) (32).

Rupture of a prior Uterine Incision

Induction of labour in a woman with a prior scar can be catastrophic. For such women, even in spontaneous labour , there is a risk of scar rupture which is three-fold. When prostaglandins and oxytocin are used in these women, the risk is 15.6 fold,

when oxytocin alone is used, it is fivefold (34) . ACOG advises against the use of prostaglandins in induction of labour in women with a scarred uterus. Foleys catheter can be used for this purpose.

Uterine Atony

Induction of labour can lead to an atonic uterus and postpartum haemorrhage. This can lead to intractable bleeding, and in certain cases, peripartum hysterectomy.

A study by Hernandez et al in Parkland Hospital showed that induction of labour was associated with 17% of the 553 women who had peripartum hysterectomies (35) .

There has been an increase in the total peripartum hysterectomies in the USA, rising from 71.6 to 82.6 per 100,000 deliveries from 1994-1995 to 2006-2007. This rise has been attributed to rising rates of induction of labour, as well as increased rates of primary/ repeat caesarean sections (36) .

Infant Morbidity

Induction of labour in early term gestations (37 to 38+6 weeks) leads to greater neonatal morbidity and greater utilization of health care services during the first year of life(37). This may not be true for those babies induced after 39 weeks, there is not much data to prove/disprove the same.

Fetal Distress

Injudicious use of Prostaglandins can lead to uterine tachysystole which may vary from 3-20% (38) .This decreases placental flow and can lead to fetal compromise, which is especially important in the background of fetal growth restriction. Studies comparing Misoprostol to Dinoprostone have not found much of a difference in rates of non reassuring fetal status between the two groups (39).

Preinduction Cervical Ripening

The 'favourability' of the cervix is an important factor when predicting the success of induction of labour. When cervix is unfavourable, there are a number of pharmacological and mechanical methods which can be used to make the cervix more favourable.

These methods are:

- Pharmacological Methods: Prostaglandin E2, Prostaglandin E1, Nitric Oxide Donors, Oxytocin
- Mechanical Methods: Transcervical catheter, Hygroscopic Cervical Dilators, Stripping of membranes, Amniotomy

Pharmacological Techniques

- **Prostaglandin E1** : Misoprostol is a Prostaglandin E1 analogue that has been approved in the strength of 100 – 200 mcgm to aid in peptic ulcer disease. It is not FDA approved for the use of induction of labour. However it is widely used as an abortifacient and in low dose as an agent for induction of labour in developing countries as the cost is low. An advantage is that the tablets are stable when kept at room temperature.

However ACOG (2013b) has reaffirmed the use of the drug for use of labour induction/ abortion due to its proven safety profile, as well as efficacy. It is the drug of choice for induction of labour at our institution.

Vaginal Administration: Many trials have been carried out, where Misoprostol has been shown to be equally, if not more efficacious than Dinoprostone for the induction of labour.

A Cochrane review studied 121 trials. There was a risk of bias, as only 13 of these were double blind. Misprostol was found to be associated with reduced failure to

achieve vaginal delivery when compared to placebo (average relative risk (RR) 0.51, 95% confidence interval (CI) 0.37 to 0.71). There was however, a higher risk of hyperstimulation, albeit without fetal heart rate changes. When compared to PGE2, Misoprostol had less incidence of epidural analgesia usage, more hyperstimulation, a higher incidence of meconium stained liquor and less failure to achieve vaginal delivery (13) .

Oral Misoprostol: Misoprostol is also effective as an oral agent, and has been found to be associated with less tachysystole/ fetal heart changes. A Cochrane review studied the use of oral Misoprostol for induction of labour. The reviewers were able to include 76 trials (14,412 women). These trials were of mixed quality. There were 9 trials (1109 women), that compared oral Misoprostol to placebo. They found that women who were given oral Misoprostol were more likely to achieve vaginal delivery within 24 hours (risk ratio (RR) 0.16, 95% confidence interval (CI) 0.05 to 0.49; one trial; 96 women). They also tended to need less oxytocin , and were less likely to need Caesarean sections.

There were 9 trials (1282 women) that compared the use of oral misoprostol to intravenous oxytocin. Those taking oral Misoprostol had a significantly lower Caesarean rate. However, they had a higher rate of meconium stained liquor.

12 trials (3859 women) compared oral misoprostol to vaginal dinoprostone. Those that received oral misoprostol had a lower probability of undergoing caesarean section (40) . 100 mcgm of oral Misoprostol and 25 mcgm of vaginal Misoprostol have similar efficacy (41).

- **Prostaglandin E2**

Dinoprostone is a synthetic analogue of PG-E2. Commercially, it is available as a time-release insert for vaginal use, a gel and a 10 milligram suppository. The first two are only indicated in the use of labour induction at term. However, the 10 mg suppository can be used for second trimester abortions, as well as termination of pregnancy in case of intrauterine death upto 28 weeks of gestational age (1) .

Local PGE2 is commonly used for cervical ripening (ACOG 2013b). The gel form is available preloaded in a syringe, which delivers 0.5 mg of Dinoprostone into the cervix, just below the internal os. This can be repeated 6 hourly, a maximum of three doses within 24 hours. The patient needs to remain lying down for at least 30 mins after application. Subsequent use of Oxytocin should be delayed by at least 6 – 12 hours. The 10mg vaginal insert is a thin polymeric wafer which is held within a small mesh polyester sac which has a long tail attached enabling easy removal from the vagina. This formulation allows for slower release of the compound – 0.3 mg/hour – when compared to the gel form. It is placed in the posterior vaginal fornix as a single dose.

The woman should then remain recumbent for 2 hours at least. Removal of the insert should take place after 12 hours, with the onset of labour and at minimum 12 hours prior to initiating oxytocin.

A Cochrane Review published in 2014 found that PGE2, when compared to placebo/ no treatment, probably reduces the likelihood of not achieving vaginal delivery in 24 hours. The risk of hyperstimulation with FHR changes is increased. The risk for having a caesarean delivery is probably decreased by about 10%. The various

formulations (gels/ pessaries/ tablets) seemed to be equally effective. Differences in acions appear to be marginal, and may be due to chance (42).

- **Prostaglandin F2Alpha**

This compound has also been used for the induction of labour. Though not much study has been done on the prostaglandin, it has been shown to increase the probability of achieving vaginal birth. There is an increase in rates of hypertonus, but this does not seem to translate to higher rates of caesarean section (42).

Prostaglandins should be used with caution in women with glaucoma or asthma. However studies show Dinoprostone may be safe in asthmatics (43).
Manufacturers advise caution when used in women with ruptured membranes, when cephalopelvic disproportion is suspected, those already on oxytocin, those with history of 6 or more term pregnancies and those with a contraindication to undergoing vaginal delivery.

- **Nitric Oxide donors**

Nitric oxide probably mediates cervical ripening (1). Hence, research has been directed to drugs that can produce this compound (glyceryl trinitrate, isosorbide mononitrate) and their potential use in induction of labour (44) . Isosorbid mononitrate also induces COX-2 enzyme in the cervix and causes cervical ripening. However, a Cochrane review which analysed 10 trials found that nitric oxide donors are not useful for ripening of the cervix. Further clinical trials are required in this field of study (45).

- **Oxytocin**

Oxytocin is produced from the hypothalamus and secreted from the posterior part of the pituitary gland. It is a polypepetide hormone and secreted in a pulsatile form. Its synthetic analogue is one of the most potent uterotonics known.

It is a known method of induction of labour (46). Administrating exogenous oxytocin in pregnancy causes uterine contractions, first demonstrable after 20 weeks. Its action increases as pregnancy advances due to increasing number of myometrial receptors to the same.

A Cochrane review (46) showed that oxytocin as an induction agent versus expectant management resulted in more vaginal deliveries, but this was not true when oxytocin was compared to vaginal prostaglandins.

Its use as an agent of augmentation is preferred in modern Obstetrics.

Mechanical Techniques

These include

- Transcervical placement of Foleys catheter
- Membrane stripping
- Hygroscopic agents
- Amniotomy

These methods have been found to have very low incidences of uterine tachysystole when compared to prostaglandins. The rate of caesarean section appears to be unchanged.

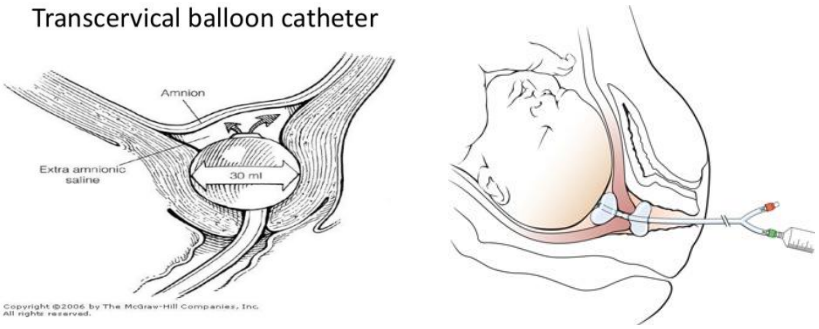
- **Transcervical Catheter**

The use of a catheter to dilate the cervix was first attributed to Barnes in the 1860's. Embrey and Mollison have since been credited with rediscovering its use in 1967 (47).

Mechanism of Action: Distension by the catheter causes release of endogenous Prostaglandins from the amnionic cells, myometrium,etc. (48) . This then causes cervical ripening. Lim et al found that insertion of a Foleys catheter causes an inflammatory reaction, and immunohistochemistry of the cervical tissue following balloon insertion shows significant increase in levels of interleukin-6 and 8, hyaluronic acid synthetase, metalloproteinase-8 and NO synthetase (49).

Two types of catheters are available - one is the Foleys catheter which is most often used (off-label use), and the other is a commercially available double balloon catheter.

Single balloon (eg. Foleys) Catheter **Double Balloon (eg. Cooks) catheter**



The double balloon catheter was developed by Atad in 1990. Simultaneous pressure against the inner and outer margins of the cervix was postulated to cause better cervical ripening than the single balloon catheter. This catheter is usually expelled at a cervical dilatation of 4 cms.

The catheters may be inflated with a volume of 30 to 80ml and kept in situ for a period of 12 hours. They are not routinely used when membranes have been ruptured, although a clinical trial, the FOLCROM study (Foley Catheter in Rupture of Membranes) is being undertaken to evaluate its use in prelabour rupture of membranes.

Risk of Infection: Cochrane review in 2012 (33 trials), concluded that there is no increased risk of infection with Foleys catheter. However, in view of limited trials, differing criteria for infection and most studies being conducted in the setting of intact membranes, this opinion should be interpreted with caution **(50)**.

A Cochrane review in 2012 compared mechanical induction of labour with various other methods. The reviewers included 71 randomised trials encompassing 9722 women.

Mechanical methods versus vaginal PGE2: Overall, there was no significant difference in the percentage of women who had vaginal delivery in the span of 24 hours. On subgroup analysis it was found that in multiparous women, the risk of not achieving delivery at all within twenty four hours was higher. There was no increase in the rate of caesarean sections.

Mechanical methods versus PGE1/ Intracervical PGE2: No significant difference in women not achieving vaginal birth in 24 hours. With mechanical methods, there was a lower rate of uterine hyperstimulation. With both mechanical methods and prostaglandins, the risk of caesarean section was comparable between the two groups. There was no significant difference in rates of severe neonatal/ maternal morbidity between the two groups (51) .

- **Hygroscopic Cervical Dilators**

These devices have osmotic properties, drawing water slowly out of the cervix, thus causing cervical dilatation. They are of various types- some derived from Lamniaria algae, others are synthetic eg. Dilapan-S, which is made up from acrylic gel. These have been in use for over 40 years, especially for termination of pregnancy. Their use

for cervical ripening is also known, although there are concerns over ascending infection, which haven't been adequately addressed. There seem to be few advantages, other than the low cost. They appear to be safe, but anaphylaxis is a rare complication (52).

- **Stripping of membranes at term**

This procedure can be done on an outpatient basis. It is a procedure by which the examining health professional inserts their finger into a partially dilated cervix and partly detaches the lower portion of the membranes in a circumferential fashion. This probably releases endogenous prostaglandins, and causes the onset of labour.

A Cochrane review analysed 22 trials (2797 women) that compared membrane stripping to either no treatment, to prostaglandins, or to oxytocin. All groups had similar risk of Caesarean section. Sweeping membranes as a general policy at term led to shorter duration of pregnancy(gestation) as well as reduced the likelihood of pregnancies going beyond 41 and 42 weeks of gestation. If one wants to avoid ONE induction of labour, one needs to sweep membranes in 8 women (number needed to treat = 8). Thus sweeping of membranes for 8 patients results in at least one of them going into spontaneous labour.

Rates of maternal/ neonatal infection were similar in the groups. However, studies wherein sweeping of membranes were compared to Prostaglandins had limited sample sizes, and did not provide any evident benefit (53).

- **Amniotomy**

Artificial rupture of membranes can be done to both induce as well as augment labour. When used as a method for induction, there is a rather unpredictable relationship between time of membrane rupture and onset of labour. This can be hastened by combining this method with use of oxytocin. Mercer et al randomized patients to either amniotomy at a dilatation of 1-2 cms with oxytocin, versus amniotomy at 5 cms, and found that early amniotomy and augmentation reduces duration of labour significantly by 4 hours. However, early amniotomy is associated with an increased rate of chorioamnionitis (54).

Failed Induction

Those who enter labour spontaneously have higher chances of achieving a vaginal delivery than those who undergo induction of labour. There is no standard definition of failed induction. The term is used when a woman fails to enter active stage of labour after 12 hours of augmentation, with adequate uterine contractions. ACOG in 2012 has proposed that failed induction should be defined as failure to generate regular contractions approximately every three minutes and cervical change after at least 24 hours of oxytocin administration (55). Cervical ripening may take place prior to oxytocin administration, with one or several doses of prostaglandins. This may extend over 1-2 days, and this time period is not included when considering failed induction.

This new definition was proposed at a workshop help in the United States in 2012 – Preventing the first cesarean delivery: summary of a joint Eunice Kennedy Shriver National Institute of Child Health and Human Development, Society for Maternal-

Fetal Medicine, and American College of Obstetricians and Gynecologists Workshop. Once patients who are induced enter into active labour, duration of active labour is similar to, if not faster, than women who come in spontaneous labour. Duration of second stage does not differ among the two groups (56).

A key point made at the workshop was that induction of labour should always be performed primarily for a medical indication. If done for non medical indications, the patient should be a minimum of 39 weeks gestational age and the cervix must be favourable, more so in nulliparous women.

Misoprostol And Foleys- Current Knowledge

Decreasing the rate of primary caesareans has always been a priority. The technique of combining Misoprostol and Foleys for induction of labour may have additive effect in the induction of labour, since both have different mechanisms of action. If this is true, it may lead to shorter induction to delivery intervals, and more chances of achieving a vaginal delivery.

Rust et al randomized singleton patients with an indication for delivery, those with an unfavourable Bishops score (<5) and no contraindication to vaginal delivery were randomly assigned to two groups – vaginal PGE1 25 mcgms every 3 hours, and intracervical Foleys catheter inflated with 50 ml sterile water plus the same dosage of PGE1. Over the period of 1 year, 81 patients were randomized, 40 to PGE1 alone, and 41 to Foleys + PGE1.

They concluded that maternal and Fetal outcomes, induction to delivery intervals and caesarean section rates did not differ between the two groups (57).

Lanka et al conducted a similar study in women >28 weeks with an indication for induction of labour, with a singleton pregnancy in cephalic presentation, Bishops score <4 with intact membranes and randomized them into two groups- Foleys + Misoprostol versus only Misoprostol. They recruited 128 women over a period of 2 years.

Their study showed no significant difference between the two groups with regard to either induction to delivery interval or rate of caesarean sections.

The rate of meconium stained liquor was higher in the misoprostol group (58).

Chung et al conducted a similar trial, with three arms- Misoprostol alone, Foleys alone or a combination of the two for the induction of labour. They included singleton pregnancies >= 28 weeks, with a bishops score of <=6.

A total of 146 patients were recruited, out of which 49 received Misoprostol, 54 received Foleys catheter and 43 patients a combination of both. They found no difference in the rate of vaginal delivery in the three groups (misoprostol, 63.3%; Foley, 57.4%; combination, 58.1%; P=.81). There also was no difference in induction to active phase intervals or induction to delivery intervals between the three groups(59).

Since the previous studies showed inconsistent results, Chen et al (16) did a meta-analysis of a total of 8 trials and 1153 patients.The studies included in this analysis were all randomized control trials on pregnant women induced with Foleys and Misoprostol with Foleys versus Misoprostol alone.

Meta-analysis of Chen et al:

Study	Inclusion criteria		F+M group,Route + Dose		M group Route + Dose	F+M Number of patients	M
	Gestation	Bishops score					
Lanka et al. 2014	≥ 28	≤ 4	16 F,30 mL	Vaginal,25 μg every 4 h	Vaginal, 25 μg every 4 h	63	63
Ugwu et al. 2013	≥ 37	≤ 5	16 F, 30 mL	Vaginal<comma> 25 μg every 4 h	Vaginal, 25 μg every 4 h	40	40
Carbone et al. 2013	≥ 24	≤ 6	unknown size,60 mL	Vaginal,25 μg every 4 h	Vaginal, 25 μg every 4 h	56	61
Hill et al. 2009	24–42	≤ 4	24 F, 50 mL	Oral, 100 μg at 4–6 h intervals	Vaginal, first dose 50 μg,then 25 μg at 3–6 h intervals	106	126
Kashanian et al. 2006	≥ 28	≤ 5	16 F,30 mL	Vaginal, 25 μg every 3 h	Vaginal,25 μg every 3 h	100	100
Chung et al. 2003	≥ 28	≤ 6	16 F, 30 ml	Vaginal, 25 μg every 3 h	Vaginal, 25 μg every 3 h	43	49
Barrilleaux et al. 2002	Not provided	≤ 7	24 F,50 mL	Oral, 100 μg every 4 h	Oral, 100 μg every 4 h	109	116
Rust et al. 2001	Term	≤ 7	24 F, 50 mL	Vaginal,25 μg every 3 hours	Vaginal, 25 μg every 3 hours	41	40

Results:

Induction to delivery interval: The combination group (F+M) was found to have a shorter mean time to delivery than the Misoprostol alone (M), but the difference was not of statistical significance (mean difference –1.46 hours, 95% CI –3.72 to 0.81; $P = 0.21$). The heterogeneity between all the studies, was however, significant.

Caesarean Delivery: The rates of Caesarean were similar in both groups.

Chorioamnionitis: Most studies either did not report on chorioamnionitis or else had

inconsistent definitions for the same. Of the 666 patients eligible for analysis, there was a significant increase in the risk for chorioamnionitis in the combination group.

Uterine tachysystole with Fetal Heart Rate changes: 5 studies reported on this outcome, and the combination group had a significantly decreased incidence of the same.

Others: There were no significant differences in the two groups for the other outcomes- endomyometritis, oxytocin augmentation, meconium stained amniotic fluid or NICU admission.

This review found that using a combination of Foleys and Misoprostol for induction of labour resulted in a shorter induction to delivery interval, less hyperstimulation and higher incidence of chorioamnionitis when compared to use of Misoprostol alone. However the studies were heterogenous, using varying definitions and regimes for induction. They were not double blinded due to inherent study design. The conclusion that chorioamnionitis is higher in the combination group should be interpreted with caution due to the few numbers of patients eligible for inclusion in this regard. The authors concluded that more studies are needed to evaluate the efficacy and safety of using these methods of cervical ripening for induction of labour.

Hence we endeavored to retest this hypothesis by conducting an adequately powered randomized quality study.

METHODOLOGY

This is a prospective, randomised control trial to study the efficacy of Foleys and Misoprostol versus Misoprostol alone for induction of labour.

The trial was presented before the Institutional Review Board in Christian Medical College, and protocol was approved prior to start of recruitment. All Primigravida, low risk, term patients coming to CMC labor room & Obstetrics wards for routine induction of labor were screened for the trial. All primigrravidas with singleton pregnancies in longitudinal lie and cephalic presentation at 37 +0 to 40+6 weeks of gestation, with a medical indication for induction, intact membranes and a Bishops score of <6 were counselled for participation in this trial. High risk pregnancies, multigravidas, non vertex pregnancies, those with fever/ sepsis, those undergoing reinduction or those with a known allergy to Misoprostol/ Latex were excluded.

Eligible women who agreed to be part of the trial, were given an information sheet and explained about details of the trial. If they agreed, they were asked to sign a consent form.

Inclusion Criteria

- Primigravida
- 37 completed weeks to 40+6 weeks of gestation
- Low risk pregnancy
- Singleton, cephalic presentation, live fetus
- Intact membranes
- Bishops Score <6 (not in labour)
- Reactuve preinduction CTG

Exclusion Criteris

- Multigravida
- Bishops Score >8
- High Risk Pregnancy
- Rupture of membranes

- Maternal fever
- Non vertex presentation
- Non reassuring CTG
- Reinduction (previously unsuccessful induction of labour)
- Allergy to Misoprostol/ latex

Patients were recruited from July 2015 to August 2016 in Christian Medical College, a 2450 bed, tertiary care, teaching hospital.

Consenting women were then subjected to a pre induction Non Stress Test, which was carried out for a minimum of 20 minutes. If this was reactive, the Principal Investigator was called in to randomise the patient.

Patients were randomly allotted to two groups – those for induction with Misoprostol plus Foleys catheter and those for induction with only Misoprotol – using computer generated randomisation codes in a 1:1 ratio using Block randomisation. Permuted

Block randomization of various proportions with block sizes of 2,4 or 6 were applied

and random sequence was generated. SAS 9.1.3 was used to generate the sequence.

Sealed, opaque envelopes were used, and the Principle Investigator was not aware of the randomisation sequence prior to actual randomisation.

However, due to the nature of treatment, after randomization, the patient, principal investigator & caregiver were aware of the arm into which the patient was allocated.

Patients in the combination arm were induced with a 16 Fr Foleys catheter inserted by registrars into the cervix and inflated with 30ml of distilled water. Simultaneously, 25 mcgm of Misoprostol was inserted into the posterior fornix of vagina, which was repeated 4 hourly for a total of 3 doses with Foleys in situ. Foleys was removed after 12 hrs of insertion, unless there was an indication to do so earlier. Patients were monitored with continuous CTG. Subsequent doses of Misoprostol were withheld if patient developed contractions, ruptured of membranes or fetal heart

became non reassuring .

Patients in the Misoprostol Only arm were induced with Misoprostol alone, 25 mcgm Q4th hourly for a total of 3 doses in the posterior fornix of vagina by registrars. Continuous CTG monitoring was done. Indications for abandoning subsequent doses were similar as in the combined treatment arm.

Baseline data was collected for these patients at recruitment, which included Body Mass Index, Age, Socioeconomic status. Additional information was collected after delivery, such as induction to delivery interval, data pertaining to the neonate, details of vaginal delivery, instrumental delivery and caesarean section. Failed induction was defined as failure to enter into the active stage of labour after 12 hours of augmentation with Oxytocin, with adequate uterine contractions.

Sample Size calculation: The required sample size to show that there is at least two and a half hours difference in the induction to delivery between the groups receiving misoprostol alone and the combination of misoprostol and foleys with 80% power and 5% level of significance was found to be 305 women in each arm. The sample size was calculated on the basis of taking average standard deviation from both groups as 11 as demonstrated by Chung et al (59)

Two Means - Hypothesis testing for two means

Standard deviation in group Misoprostol alone	11
Standard deviation in group Misoprostol + Foley	11
Mean difference	2.5
Effect size	0.227273
Alpha error (%)	5
Power (1- beta) %	80
1 or 2 sided	2
Required sample size per group	304

Statistical Analysis:

Table

	Inclusion Criteria
1.	Primigravida
2.	37 completed weeks to 40+6 weeks gestational age
3.	Low risk pregnancy
4.	Singleton, cephalic presentation, live fetus
5.	Intact membranes
6.	Bishop score < 6(not in labor)
7.	Reactive pre induction CTG

Table

	Exclusion Criteria
1.	Multi gravid
2.	Bishops score **>8**
3.	High Risk Pregnancy
4.	Rupture of membranes
5.	Maternal fever
6.	Non vertex presentation
7.	Non reassuring CTG
8.	Reinduction (previously unsuccessful induction of labour)
9.	Allergy to misoprostol/latex

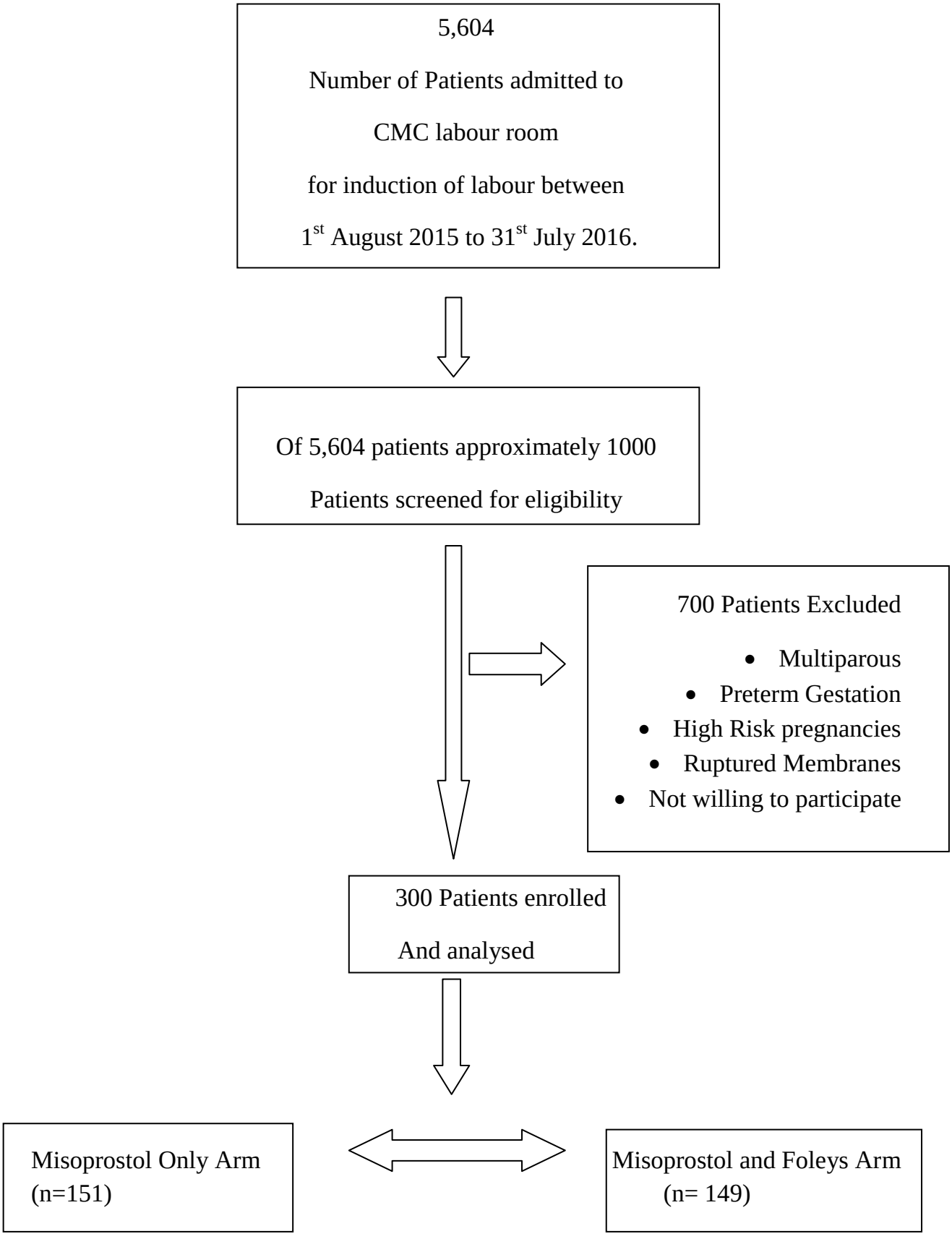
RESULTS

A total of 14,957 patients were admitted to the CMC Labour room from 1st August 2015 to 31st July 2016, of which 5,604 were admitted for induction of labour. According to the convenience of the principal investigator approximately 1000 patients were screened. Of which 300 patients were randomized after fulfilling the inclusion and exclusion criteria. Remaining patients were excluded as they were multiparous, preterm in gestation not willing for participation in trial or had high risk factors such as pre-eclampsia.

A total of 300 patients were recruited into the study. Of these, 151 patients were induced with Misoprostol only and 149 patients were induced with Misoprostol and Foleys catheter.

The baseline characteristics are shown in Table 3. The groups were similar in age, except for the age group of >30 years, which had more patients randomised to the Misoprostol and Foleys group. 172 patients (57.3%) were from Vellore, 70 patients (23.3%) were from the rest of Tamil Nadu and 58 patients (19.3%) from outside Tamil Nadu. There were about 49.7% patients with a BMI of >25 kg/m2 in the Misoprostol arm, and 39.6% in the Misoprostol and Foleys arm. 41 patients (27.3%) had anemia, and 36 patients (12%) had primary infertility. The group randomised to the Misoprostol arm had 85 patients (55.6%) with a Bishops score of < 3 and 66 patients (43.7%) with a Bishops score of >3, but in the Misoprostol and Foleys group, there were more patients with Bishops score of <3 (79.2%) compared with Bishops score >3 (20.8%).

Patient Flow Chart



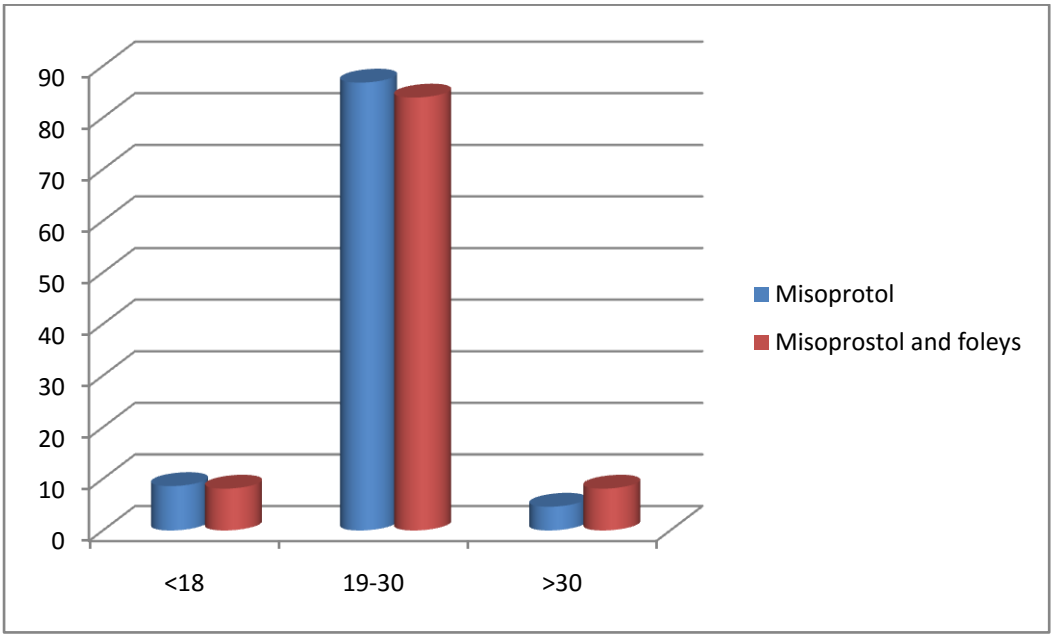
BASELINE CHARACTERISTICS

Table No. 1

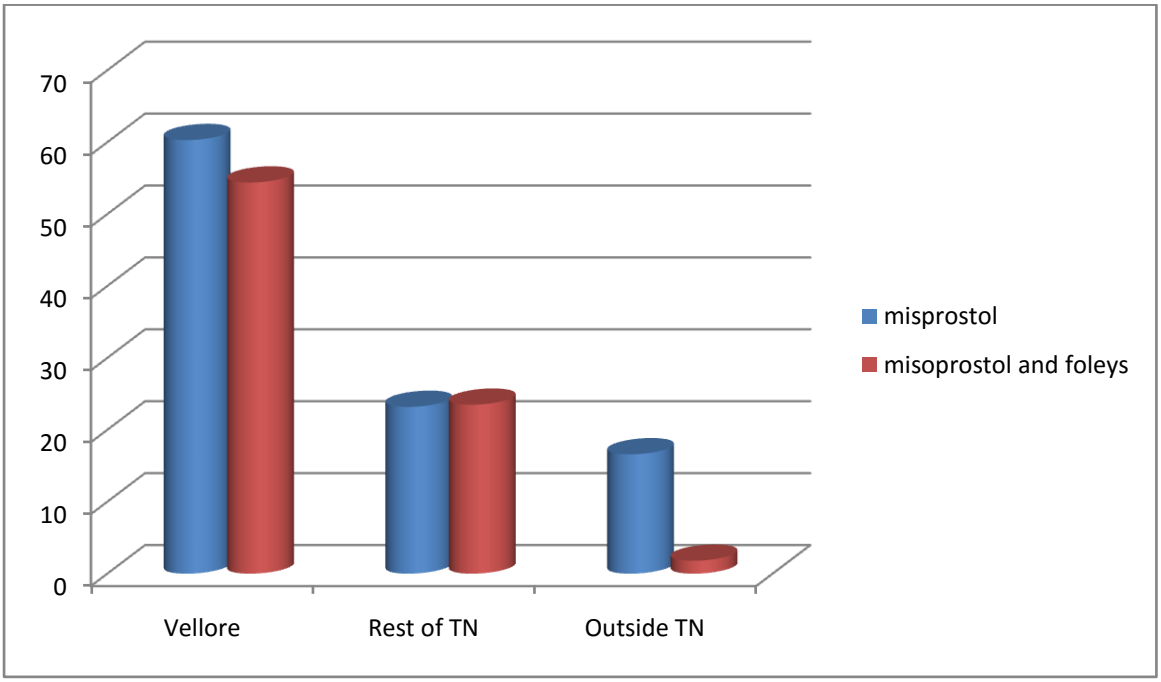
BASELINE CHARACTERISTICS

DEMOGRAPHIC DATA	Misoprostol alone	Misoprostol and Foleys	Total
1. Age(years) • <18 • 19-30 • >30	 13(8.6%) 131(86.8%) 7(4.6%)	 12(8.1%) 125(83.9%) 12(8.1%)	 25(8.3%) 256(85.3%) 19(6.3%)
2. Hometown • Vellore • Rest of Tamil Nadu • Outside Tamil Nadu	 91(60.3%) 35(23.2%) 25(16.6%)	 81(54.4%) 35(23.5%) 33(22.1%)	 172(57.3%) 70(23.3%) 58(19.3%)
3. BMI • <18.5 • 19.5-24.9 • 25-29.9 • 30>	 4(2.6%) 72(47.7%) 61(40.4%) 14(9.3%)	 2(1.3%) 88(59.1%) 45(30.2%) 14(9.4%)	 6(2.0%) 160(53.3%) 106(35.3%) 28(9.3%)
4. ANTENATAL RISK FACTORS			
Primary infertility	22(14.6%)	14(9.4%)	36(12.0%)
Elderly	10(6.6%)	14(9.4%)	24(8.0%)
Anemia	24(15.9%)	17(11.4%)	41(13.7%)
5. BISHOPS SCORE AT INDUCTION • 2 & 3 • 4,5,6	 85(55.6%) 66(43.7%)	 118(79.2%) 31(20.8%)	 203(67.3%) 97(32.3%)

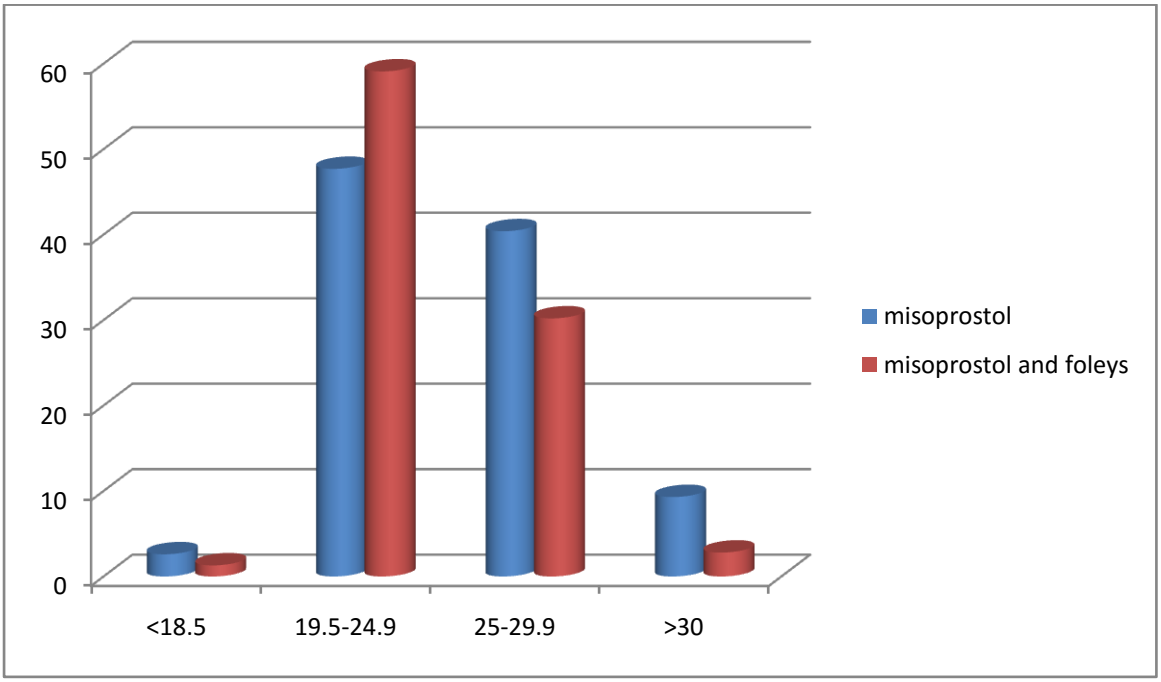
Graph 1- AGE WISE DISTRIBUTION (%)



Graph 2- Domicile Status

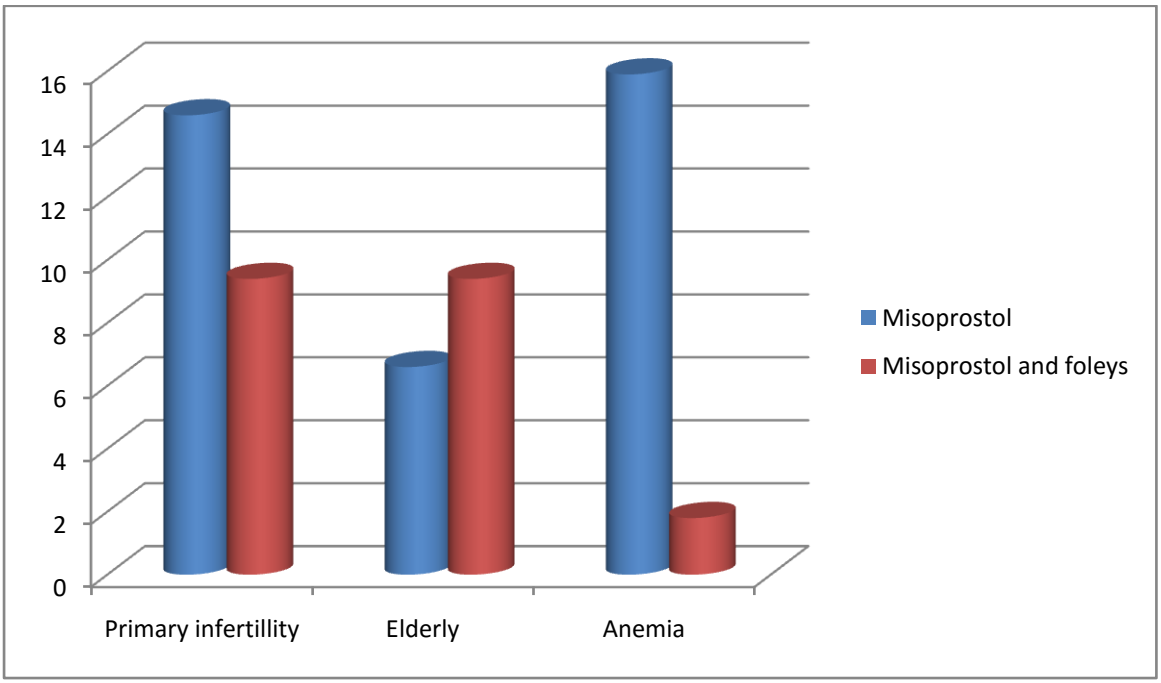


Graph 3 – BODY MASS INDEX



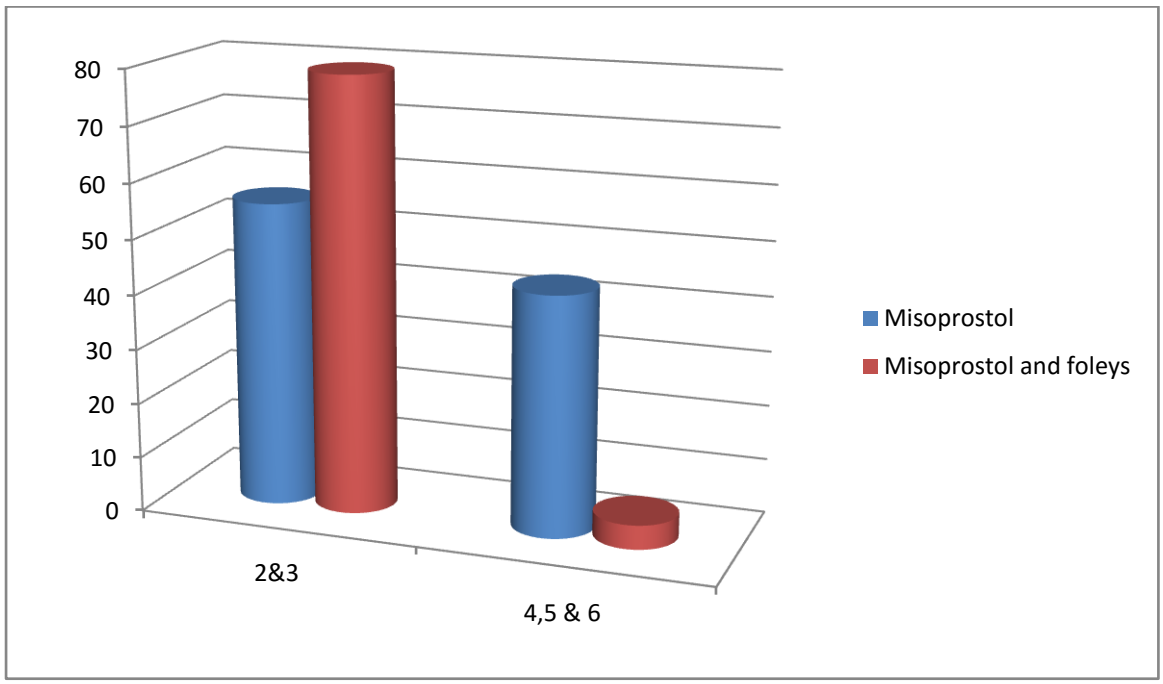
Risk Factors – High risk patients were excluded from the study. There were more patients with Primary Infertility in the Misoprostol only arm (22 versus 14), more patients with anemia in the Misoprostol only arm (24 versus 17), and more elderly patients in the Misoprostol and Foleys arm (14 versus 10).

GRAPH 4 – MATERNAL RISK FACTORS



Bishops Score at induction- There were more patients with a Bishops score of 2 or 3 randomised to the Misoprostol and Foleys arm compared to the Misoprostol only arm (118 versus 85). Those with a higher Bishops score (4,5 or 6) were randomised in larger numbers to the Misoprostol only arm (66 versus 31 patients).

Graph 4 – BISHOPS SCORE AT INDUCTION



OUTCOME MEASURES

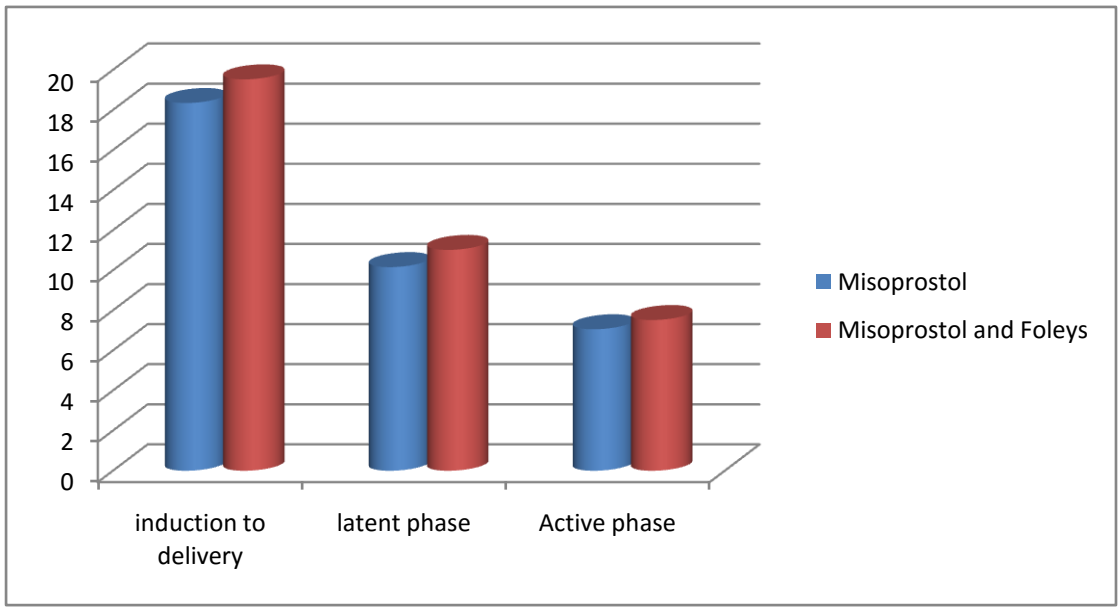
Primary Outcomes

There was a shorter induction to delivery interval in the Misoprostol only arm by 1 hour 18 minutes compared to the Misoprostol and Foleys arm. This difference was statistically significant (p value 0.017). The latent phase of labour was found to be shorter by 1 hour and 16 minutes in the Misprostol only group (p value 0.001). The active phase of labour was also shorter in the Misoprostol only group by 44 minutes. Though this was not statistically significant (p value – 0.38), this is of clinical importance. Shortened active phase of labour may help reduce infectious morbidity, the strain on the mother and the baby, as well as allow greater turnover in institutes where patient load is greater and doctors are hard pressed for empty beds.

Table No. 2 – **Induction to Delivery interval**

Outcome Measures	Misoprostol Only Arm	Misoprostol and Foleys Arm	'p'value
Induction to Delivery Interval (hours)	18.35	19.53	0.017
Latent phase of labour (hours)	10.16	11.02	0.001
Active phase of labour (hours)	7.08	7.52	0.386

Graph 5 – **Induction to Delivery interval** .



Gestational Age and Bishops Score

The following table shows randomisation in the two groups according to Gestational Age and Bishops Score.

Table No. 3 - **Gestational age and bishop score**

Gestational Age	Misoprostol Only Arm (%)	Misoprostol and Foleys Arm (%)	Total (%)
1. 37 +0/7 to 38 + 6/7 weeks			
- For Bishops score -2 &3	2(66.7)	3(42.9)	5(50%)
- For Bishops Score 4,5,6	1(33.3)	4(57.1)	5(50%)
2 For 39 +0/7 to 41 +0/7 weeks			
- For Bishops score -2 &3	83(56.1)	115(81)	198(68.3)
- For Bishops Score 4,5,6	65(43.9)	27(19)	92(31.7)

Bishops score and duration of labor in each arm

When patients with Bishops Score of 2 or 3 were randomised, there were a higher number of patients randomised to the Misoprostol and Foleys arm (118 patients), as compared to the Misoprostol only arm (85 patients). In the combination arm, patients were in the latent phase of labour for 30 minutes longer than those randomised to the Misoprostol only arm. Corrected values showed a difference of 30 minutes between both arms, with a 'p' value of 0.35 Given the theoretical synergistic benefit of adding Misoprostol to Foleys induction, one would have expected these patients to have a shorter latent phase.

Table No. 4 - **Bishops score and duration of labor in each arm.**

Randomisation Arm	Latent Phase(hours)	Active Phase(hours)	Total Duration(hours)
Misoprostol			
- For Bishops score -2 &3	11.20	7.48	19.49
- For Bishops Score 4,5,6	9.32	6.55	16.88
Misoprostol with Foleys			
- For Bishops score -2 &3	11.22	7.62	20.08
- For Bishops Score 4,5,6	10.27	7.13	17.46

SECONDARY OUTCOMES

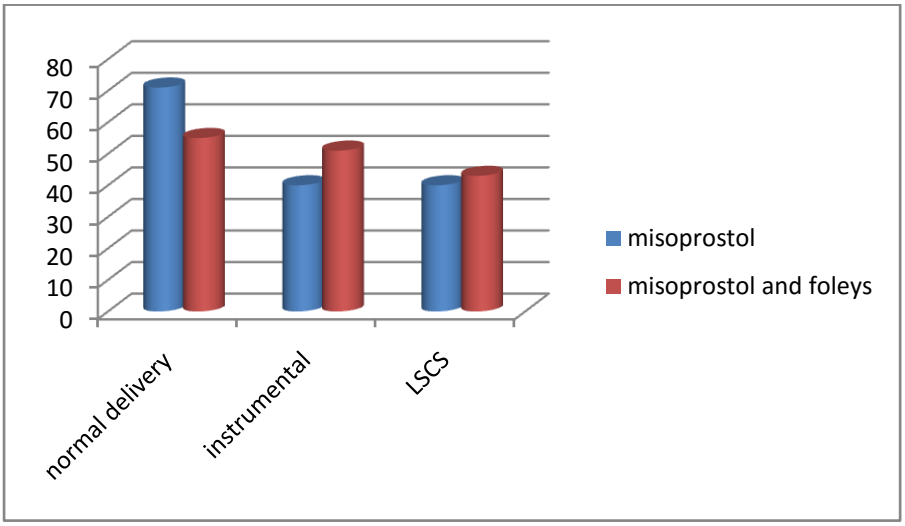
Mode of Delivery

111 of the patients in the Misoprostol only arm had a vaginal delivery, of which 40 required instrumentation. In the Misoprostol and Foleys arm, 106 had a vaginal delivery, of which 51 required instrumentation. The LSCS rate was similar in both arms – 26.5% in the Misoprostol only arm and 28.9% in the Misoprostol and Foleys arm.

Table No. 5 – **Mode of Delivery**

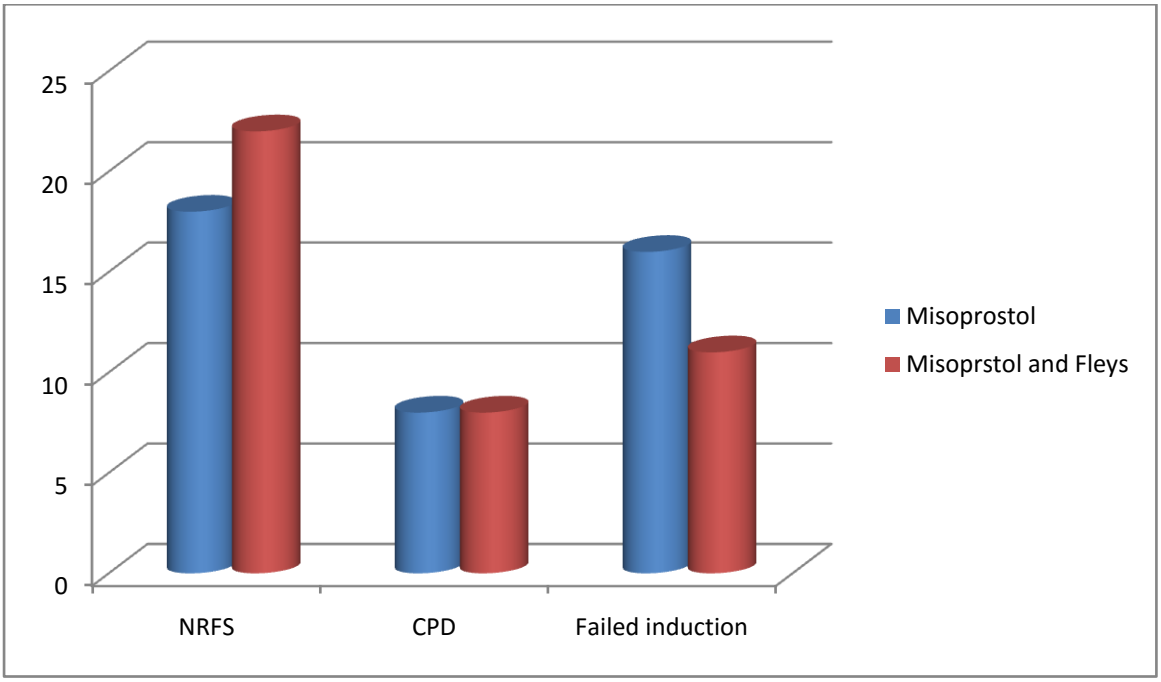
Mode of Delivery	Misoprostol Only Arm	Misoprostol and Foleys Arm	Total	'p'value
Spontaneous Vaginal Delivery				
-normal	71(47.0%)	55(36.9%)	126(42.0%)	
-instrumental	40(26.5%)	51(34.2%)	91(30.3%)	0.178
-lscs	40(26.5%)	43(28.9%)	83(27.7%)	
Caesarean Section				
Indications				
- NRFS	18(11.9%)	22(14.8%)	40(13.3%)	
- Arrest Disorder/ CPD	8(5.3%)	8(5.4%)	16(5.3%)	
- Failed Induction	16(10.6%)	11(7.4%)	27(9.0%)	0.725

Graph 6 – **Mode of Delivery**



Majority of the Caesarean Sections were done for NRFS. Other indications were arrest disorders/ CPD and Failed induction.

Graph 7 – **Indications for LSCS**



Epidural Use

Epidural use was a potential confounding factor as its use is known to prolong labour. Epidural use was found to be similar in both groups.

Table 6 –**Epidural Use**

	Misoprostol Only Arm	Misoprostol and Foleys Arm	Total	'p'value
Epidural Use	17(11.3%)	16(10.7%)	33(11.0%)	0.886

Meconium stained amniotic fluid

More patients in the Misoprostol only arm had meconium stained fluid compared to those in the Misoprostol and Foleys arm (40- 28.5% versus 14 – 10%). These findings are statistically significant, with a p value of 0.001%. Of those in the Misoprostol arm, 19.9% had thin meconium and 6.6% had thick meconium. In the Misoprostol and Foleys arm, 8.7% had thin meconium and 1.3% had thick meconium.

Table 7 – **Meconium Stained Liqour**

	Misoprostol Only Arm	Misoprostol and Foleys Arm	Total	'p'value
Meconium Stained Liqour - Thin Meconium - Thick Meconium	 30(19.9%) 10(6.6%)	 13(8.7%) 2(1.3%)	 43(14.3%) 12(4.0%)	0.001

There were a higher number of Caesareans and Instrumental deliveries in those pregnancies complicated by meconium stained liquor. Of all the patients with meconium staining, 40 were in the Misoprostol Arm. 25 of these patients underwent LSCS/ Instrumental deliveries whereas15 underwent spontaneous vaginal delivery.

There were fifteen patients in the Misoprostol and Foleys arm with meconium staining. 14 of these underwent LSCS/ Instrumental deliveries and only 1 patient had a spontaneous vaginal delivery.

Table 8 – **Meconium stained Liqour and Mode of Delivery**

Meconium stained liquor	Mode of delivery Normal	Instrumental	LSCS	Total	'p' value
Misoprostol arm					
Thin msaf	14(19.7%)	7(17.5%)	9(22.5%)	30(19.9%)	0.157
Thick msaf	1(1.4%)	4(10.0%)	5(12.5%)	10(6.6%)	
Misoprostol with Foleys arm					
Thin msaf	1(1.8%)	5(9.8%)	7(16.3%)	13(8.7%)	0.034
Thick msaf	0(0.0%)	2(3.9%)	0(0.0%)	2(1.3%)	

Hyper- stimulation warranting use of Terbutaline

More patients in the Misoprostol only arm had hyperstimulation requiring the use of Terbutaline compared to those in the Misoprostol and Foleys arm (21 patients- 13.9% versus 15 patients - 10.1%). This difference was not statisitically significant.

Table 9 – **Hyperstimulation warranting use of terbutaline**

	Misoprostol Only Arm	Misoprostol and Foleys Arm	Total	'p' value
Hyper- stimulation warranting use of Terbutaline				
-yes	21(13.9%)	15(10.1%)	36(12.0%)	0.306
-no	130(86.1%)	134(89.9%)	264(88.0%)	

Hyperstimulation and mode of delivery

The higher rate of hyperstimulation in the Misoprostol only group is reflected in a higher rate of Caesarean Section rates in this group compared to Misoprostol and Foleys arm (35% versus 18.6%). This difference was statistically significant.

Table 10 - **Hyperstimulation and mode of delivery**

Hyperstimulation – terbutaline use	Mode of delivery			Total	'p' value
	normal	instrumental	LSCS		
Misoprostol arm	4(5.6%)	3(7.5%)	14(35.0%)	21(13.9%)	<0.001
Misoprostol with Foleys arm	3(5.5%)	4(7.8%)	8(18.6%)	15(10.1%)	0.081

Incidence of Chorioamnionitis

The incidence of chorioamnionitis did not differ markedly in the two groups.

Table 11- **Incidence of chorioamnionitis**

	Misoprostol Only Arm	Misoprostol and Foleys Arm	Total	'p' value
Incidence of Chorioamnionitis -yes -no	7(4.6%) 144(95.4)	9(6.0%) 140(94.0%)	16(5.3%) 284(94.7%)	0.588

Post Partum Haemorrhage

There were 12 patients in the Misoprostol only group with post partum haemorrhage compared to 13 patients in the Misoprostol and Foleys group, this difference was not significant.

Table 12 – **Post Partum Haemorrhage**

	Misoprostol Only Arm	Misoprostol and Foleys Arm	Total	'p' value
Atonic PPH	12(7.9)	13(8.7)	25(8.3)	0.886

Post partum complications – Maternal

The incidence of endomyometritis was higher in the Misoprostol arm compared to Misoprostol and Foleys (9 patients, 6% versus 4 patients, 2.7%). Wound infection was slightly higher in the Misoprostol and Foleys arm – 12 patients, 4% compared to Misoprostol only arm – 4 patients, 2.6%. Neither of these findings was statistically significant. One patient in the Misoprostol and Foleys arm developed pneumonia. UTI occurred in both groups in equal measure.

Table 13 - **Post Partum Complications in the mother**

	Misoprostol Only Arm	Misoprostol and Foleys Arm	'p'value	Total
Puerperal Fever				
- UTI	5(3.3%)	6(4.0%)	11(3.7%)	
- Endomyometritis	9(6.0%)	4(2.7%)	13(4.3%)	0.358
- none	133(88.1%)	130(87.2%)	263(87.7%)	
- Wound infection (LSCS/ Episiotomy)	4(2.6%)	8(5.4%)	12(4.0%)	
- Pneumonia	0(0.0%)	1(0.1%)	1(0.3%)	

Obesity affecting the duration of labour

For a BMI of 18.5 to 24.9 kg/m2, there was no statistically significant difference between the two groups. There was 58 minutes reduction in the duration of the latent phase in the Misoprostol only group as compared to the Misoprostol and Foleys group. Active phase was also shorter in the Misoprostol only group by 22 minutes.

Table 14 - **BMI – 18.5 – 24.9 kg/m2:**

Randomisation Arm	Latent Phase(hours)	Active Phase(hours)	Total Duration(hours)
Misoprostol	10.29	7.36	18.48
Misoprostol with Foleys	11.27	8.28	19.33
P value	0.15	0.290	0.668

For a BMI of 25 to 29.9 kg/m2, there was a statistically significant difference between both the latent and the active phase of labour, both being significantly shorter in the Misoprostol only arm. The latent phase was shorter by 1 hour 51 minutes (p value 0.001) and the active phase by 35 minutes (p value 0.002). The total duration of labour was thus reduced by 2 hours 39 minutes in the Misoprostol only group.

Table 15 - **BMI – 25- 29.9 kg/m2**

Randomisation Arm	Latent Phase(hours)	Active Phase(hours)	Total Duration(hours)
Misoprostol	10.25	7.35	18.32
Misoprostol with Foleys	11.36	7.30	20.31
P value	0.001	0.002	0.369

For a BMI of >30, there was a reduction in the duration of the latent phase by 37 minutes and active phase by 28 minutes for the Misoprostol only group. The overall duration of labour was 2 hours and 16 minutes less than the Misoprostol and Foleys group. However, this difference was not statistically significant.

Table 16 – **BMI >30 kg/m2**

Randomisation Arm	Latent Phase(hours)	Active Phase(hours)	Total Duration(hours)
Misoprostol	11.19	6.18	20.19
Misoprostol with Foleys	11.22	6.30	18.03
P value	0.401	0.210	0.734

SECONDARY OUTCOMES – NEONATAL

There were 4 babies with a low Apgar (<5,7) in the Misoprostol only arm, and only 1 baby with low Apgar in the Misoprostol and Foleys group. This was not statistically significant. Neonatal ICU admission rate was almost identicial in the two groups. More babies in the Misoprostol group (27 babies, 17.9%) were diagnosed with neonatal sepsis compared to the Misoprostol and Foleys arm (20 babies, 13.4%).

Table 17 – **Neonatal outcomes**

Outcome Measure	Misoprostol Only Arm	Misoprostol and Foleys Arm	'p'value	Total
APGAR score - >5,7 - <5,7	 147(97.4%) 4(2.6%)	 148(99.3%) 1(0.7%)	 295(98.3%) 5(1.7%)	 0.181
NICU Admission -yes -no	 10(6.6%) 141(93.4%)	 9(6.0%) 140(94.0%)	 19(6.3%) 281(93.7%)	 0.836
Neonatal Sepsis - Culture Proven - Probable Sepsis - No sepsis	 6(4.0%) 21(13.9%) 124(82.1%)	 2(1.3%) 18(12.1%) 129(86.6%)	 8(2.7%) 39(13.0%) 253(84.3%)	 0.314

DISCUSSION

This study recruited 300 patients over the period of 1 year from July 2015 to August 2016. Of these patients, 151 were recruited to the Misoprostol arm and 149 patients to the Misoprostol and Foleys Arm. Only Primigravidas with low risk pregnancies were eligible for this trial.

The baseline characteristics of our two groups were similar with regard to age, BMI and risk factors such as anemia and advanced maternal age. There were more patients with primary infertility in the Misoprostol only arm, however this is unlikely to have bearing on the results. Majority of our patients were from Vellore.

Majority of our patients were in the BMI range of 19.5 to 24.9 kg/m2: 72 patients (47.7%) in the Misoprostol only arm and 88 patients (59.1%) in the Misoprostol and Foleys arm. There were 61 patients (40.4%) in the Misoprostol arm and 45 patients (30.2%) in the Misoprostol and Foleys arm in the BMI range of 25 – 29.9. 20.3% of patients had a BMI of <18.5kg/m2. And 28 patients (9.3%) had a BMI of >30kg/m2.

We hypothesized that combining Misoprostol and Foleys catheter for induction of labour, through their synergistic effect, would shorten induction to delivery interval and the overall duration of labour.

Our findings are contrary to this hypothesis.

There was a shorter induction to delivery interval in the Misoprostol only arm by 1 hour 18 minutes compared to the Misoprostol and Foleys arm. This difference was statistically significant (p value 0.017). The latent phase of labour was found to be

shorter by 1 hour and 16 minutes in the Misprostol only group (p value 0.001). The active phase of labour was also shorter in the Misoprostol only group by 44 minutes. Though this was not statistically significant (p value – 0.38), this is of clinical importance. Shortened active phase of labour may help reduce infectious morbidity, the strain on the mother and the baby, as well as allow greater turnover in institutes where patient load is greater and doctors are hard pressed for empty beds.

Rust et al, Lanka et a and Chung et al , in similar trials, found no difference in induction to delivery intervals between the two groups. These trials had smaller sample size (81, 128 and 146 respectively). . Chen et al (16) in the meta analysis of 8 trials and 1153 patients, found that the combination group had a shorter induction to delivery interval by 1hour 46 minutes than the Misoprostol only group, which was not statistically significant (p value 0.21). Our findings are contrary to this, may be because our sample size is smaller (300 patients), and target sample size is yet to be reached.

There were more patients with a Bishops score of 2 or 3 randomised to the Misoprostol and Foleys arm compared to the Misoprostol only arm (118 versus 85). Those with a higher Bishops score (4,5 or 6) were randomised in larger numbers to the Misoprostol only arm (66 versus 31 patients).

Gestational age wise, for patients from 37+0/7 to 38+6/7 weeks, there were 5 patients each with a Bishops score of 2/3 and 4/5/6. Of the Bishops score of 2 or 3, two patients were in the Misoprostol arm and 3 patients were in the Misoprostol and Foleys arm. Of a Bishops score of 4,5 or 6; there was one patient in the Misoprsotol arm and 4 patients in the Misoprostol and Foleys arm. Above 39 weeks to 41+0/7

weeks, there were 198 patients (68.3%) with Bishops score of 2 and 3 compared to 92 patients (31.7%) with a Bishops score score

Inspite of randomisation of the sample, only 85 patients (55.6%) with a Bishops score of 2 and 3 were in the Misoprostol arm. In contrast, there were 118 patients (79.2%) with a Bishops Score of 2 and 3 in the Misoprostol and Foleys arm. Despite this uneven distribution, it was found that those patients with a lower Bishops score in the Misoprostol only arm had a significantly shorter latent phase of labour (30 minutes, p value 0.35). As stated earlier, Chen et al in his metanalysis found that combination arm reduced the overall duration of labour, although relation to the Bishops score is unknown.

There were more patients with meconium stained liquor in the Misoprostol only arm (40 patients, 26.5%) compared to the Misoprostol and Foleys arm (15 patients, 9.4%). These findings were statitistically significant (p value 0.001). Although the rates of meconium staining were higher in the mata analysis done by Chen et al, this was not statistically significant. Lanka et al found a higher rate of meconium staining in the Misoprostol group.

More patients with meconium stained liquor ultimately underwent Caesarean sections/ Instrumental deliveries. Of the 40 patients in the Misoprostol arm with meconium staining, 21.2% underwent normal vaginal delivery, whereas 62.5% had either Instrumental/ Caesarean delivery. These findings were statistically significant, with a p value of 0.157. Of the 15 patients with meconium stained liquor in the Misoprostol and Foleys arm, only one patient had a normal vaginal delivery whereas 14 patients underwent either Instrumental or LSCS deliveries. These findings were

also statistically significant (p value 0.034). Other studies (Lanka et al, Rust et al, Chen et al) did not find a statistically significant difference in the rates of Vaginal/ Instrumental/ Caesarean deliveries in the two groups.

21 patients (13.9%) in the Misoprostol arm required Inj. Terbutaline for hyperstimulation as compared to 15 patients (10.1%) in the Misoprostol and Foleys arm. However, this difference was not found to be statistically significant (p value 0.3). Cheng et al analysed 5 trials that studied this outcome and found the the combination group had a significantly decreased incidence of tachysystole.

Women in the BMI range of 25 to 29.9 kg/m2 had a statistically significant reduction in both the latent and the active phase of labour, both being significantly shorter in the Misoprostol only arm. The latent phase was shorter by 1 hour 51 minutes (p value 0.001) and the active phase by 35 minutes (p value 0.002). The total duration of labour was thus reduced by 2 hours 39 minutes in the Misoprostol only group.

Although labour was shorter in BMI of <25 and >30 kg/m2 for the Misoprostol only arm, this was not statistically significant.

The incidence of chorioamnionitis was nearly equal in both arms contrary to the findings in Chen et al meta analysis where combination arm had higher incidence of chorioamnionitis.

Post partum haemorrhage was slightly higher in the Misoprostol only group, but this was not statistically significant.

Endomyometritis seemed to be more frequent in the Misoprostol Only arm, and wound infections more common in the Misoprostol and Foleys arms. Neither of these findings reached statistical significance.

More babies in the Misoprostol group (27 babies, 17.9%) were diagnosed with neonatal sepsis compared to the Misoprostol and Foleys arm (20 babies, 13.4%), however this was not statistically significant.

When using Misoprostol alone, there is a higher risk for meconium staining of liquor, hyperstimulation and ultimately Caesarean section/ Instrumental deliveries.
In conclusion, according to our findings inducing labour in low risk primigravidas with Misoprostol alone is beneficial as it has shorter induction to delivery intervals and shorter overall time in labour (by 2 hours) as compared to patients induced with Misoprostol and Foleys. In women who are overweight (BMI 25 to 29.9 kg/m2, labour is 2 hours 39 minutes shorter.

CONCLUSIONS

- Misoprostol alone seems to have the following advantages as compared to misoprostol with Foleys together :
    1. Shorter induction to delivery interval
    2. Shorter overall duration of labour
    3. Useful in unfavourable cervix (bishop score < 4)
    4. After subgroup analysis, in overweight women (BMI 25 to 29.9 kg/m2), it shortened duration of labour(statistically significant)
- Even though these findings are statistically significant in our study, our numbers are underpowered to advocate Misoprostol as the best agent for induction of labour.

- Use of Misoprostol alone results in higher rates of Meconium stained liquor, hyperstimulation requiring Terbutaline and subsequently a higher Caesarean rates/ Instrumental deliveries in these patients.

- There is no statistical difference in infectious and neonatal morbidity in the two groups.

LIMITATIONS

- The main limitation of this study was that we were unable to achieve target sample size of 620 in the time period of one year. We will be continuing this study, and hope to achieve target sample size.

- Due to the inherent study design, we were unable to blind caregivers and patients to the arm in which the patient was randomised.

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ANNEXURE
Proforma Misofol

1. Name

3. Hospital Number

4. Age (in years)

5.randomisation arm

6. place

7. Gestational age in weeks

8.BMI(kg/m2)

9. bishop score

10. induction to active labor(hrs)

11. active labor to delivery(hrs)

12. induction to delivery(hrs)

13. epidural use	1. yes	2. no
14. hyperstimulation/terbutaline use	1. yes	2. no
15. mode of delivery	1. normal	2. instrumental
16. indication for lscs		
17. sex of baby	1. boy	2. girl
18. weight of baby(kg)		
19.maternal complications	1. chorioamnionitis	2. pph
20. If maternal fever, focus of infection	1. Endometritis	2. UTI
21. Admission to ICU for mother	1. Yes	2. No
22. Neonatal sepsis	1. Culture Proven	2. Probable sepsis

Informed Consent form to participate in a research study

Study Title: **Misofol**

Study Number:

Subject's Initials: _____ Subject's Name: _____

Date of Birth / Age:_____

Please initial box

(Subject)

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am

free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:_____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name: _____

Signature of the Witness: _____

Date:_____/_____/_____

Name of the Witness: _____

Patient Information Sheet

Your Doctor has decided that it is time to deliver your baby.

For the process of labour to begin, the cervical part (mouth) of the uterus needs to be softened. This can be done in two ways- by inserting a tube filled with fluid to distend the mouth of the uterus (Foleys catheter), by a tablet (Misoprostol) or by a combination of these two methods.

We are conducting a study which seeks to compare the efficacy of Foleys combined with Misoprostol versus Misoprostol alone.

You are being invited to participate in this study.

You will have no benefits or major complications by being part of this study. However, for some reason if you do not choose to be part of this study you will have no disadvantage. **Very few patients may have infection of the uterus which is treatable with antibiotics**. You always have the option of withdrawing from the study without your medical care being affected.

SPSS data entry variables

Name	Hospi no	ser no	Rand no	age	place	BMI	BS	risk	GA	latent ph	total durat	act ph	MSAf	Epid	use hyperst	mode deli	ind of lscs	chorio	fever	nicu admission	apgar
pavani	019225	g	1	1	2	1	2	1	5	2	12.00	21.32	9.32	2	2	2	2	1	3.32	4	2	3
											4	2	3	1	1	3						
sumathi	044055	c	2	2	2	2	5	1	4	2	11.40	18.49	7.09	2	2	2	2	1	3.52	4	2	3
											4	2	3	1	1	3						
sudha	047382	g	3	1	2	3	4	2	5	2	10.15	16.27	6.12	2	2	2	1	2	3.13	4	2	3
											4	2	3	1	1	3						
vidhya	241960	g	4	1	2	1	2	1	1	2	12.00	26.00	5.00	2	2	2	3	2	3.90	3	2	3
											4	2	3	1	1	3						
monika	188520	g	5	2	2	1	4	2	1	2	13.35	17.40	5.05	1	2	2	1	2	3.19	4	2	3
											4	2	3	1	1	1						
ezhil	122829	f	6	2	2	3	4	1	1	2	12.00	24.00	0.00	2	2	2	3	2	3.02	3	2	3
											4	2	3	1	1	3						
pramila	297912	g	7	1	2	1	2	2	1	2	7.30	11.45	4.15	1	2	1	1	2	3.04	4	2	3
											4	2	3	1	1	2						
yamuna	220399	g	8	2	2	1	4	1	1	2	16.15	28.10	12.05	2	1	1	3	1	2.72	1	1	1
											4	2	2	1	1	3						
sudha	931818	f	9	1	3	3	4	1	3	2	10.30	26.30	16.00	2	2	2	3	1	3.48	3	2	3
											4	2	2	1	1	3						

vaitheswar		340936g		10	2	2	1	5	1	2	2	
	12.00	30.00	0.00	1	1	2	3	2	3.46	3	2	1
	5	2	3	1	1	1						
rani		143610g		11	1	2	1	2	1	1	2	
	12.00	18.30	6.30	2	2	2	1	2	3.28	4	2	3
	4	2	3	1	1	3						
getchyl		146469g		12	2	2	1	2	1	1	2	
	10.00	26.00	16.00	2	1	2	3	2	3.50	3	2	3
	4	2	3	1	1	3						
hemalatha		147753g		13	1	2	1	2	2	1	2	
	11.00	20.10	9.10	1	2	2	3	2	3.52	1	2	3
	4	2	3	1	1	1						
archana		193996g		14	1	2	1	2	2	1	2	
	9.30	16.00	6.30	1	2	2	1	1	2.80	4	2	3
	4	2	3	1	1	1						
aruna		760091f		15	2	3	1	5	1	4	2	
	13.30	18.00	4.30	1	1	2	2	2	2.70	4	2	3
	4	2	3	1	1	1						
jeeva		186874g		16	1	2	1	4	1	2	2	
	16.00	22.30	6.30	2	1	2	2	1	3.24	4	2	3
	5	2	2	1	1	3						
hema		153424g		17	2	2	3	4	1	1	2	
	10.00	20.42	10.42	2	2	2	3	1	2.92	1	2	3
	4	2	3	1	1	3						
kalaivani		155490g		18	1	2	1	2	2	1	2	
	11.00	21.00	12.00	2	2	2	3	1	3.18	2	2	3
	4	2	3	1	1	3						
esther		155584g		19	2	2	1	2	1	1	2	
	12.00	20.00	8.00	2	2	2	3	2	3.40	2	2	3
	4	2	3	1	1	3						
deepika		364346g		20	1	2	3	4	1	5	2	
	13.30	16.00	2.30	1	1	1	3	2	2.92	1	1	1
	3	1	2	1	1	2						

naveena	208606g		21	2	2	3	2	2	1	2		
	16.00	21.15	5.15	1	2	1	2	2	2.93	4	2	3
	4	2	3	1	1	1						
madhapalli	198218g		22	1	3	3	4	2	3	2		
	10.00	17.35	7.35	2	1	2	2	2	2.92	4	2	3
	4	2	3	1	1	3						
miruna	260983g		23	2	2	3	2	2	1	2		
	13.15	17.45	4.30	2	2	2	2	2	3.06	4	2	3
	4	2	3	1	1	3						
arti	259170g		24	1	1	1	2	2	5	2		
	6.00	9.15	3.15	1	2	1	2	2	2.80	4	2	3
	4	1	1	2	1	1						
devi	395765g		25	1	2	1	4	1	2	2		
	6.00	10.30	4.30	2	2	2	3	2	3.80	2	2	3
	4	2	3	1	1	3						
priyanka	279090g		26	2	2	2	4	1	2	2		
	6.00	10.15	4.15	1	2	1	3	2	2.60	1	2	3
	5	1	2	1	1	1						
krishna	769424f		27	2	2	2	2	1	1	2		
	12.00	30.00	0.00	2	1	2	3	1	3.58	3	2	3
	4	2	3	1	1	3						
shanbag	163936g		28	1	2	1	2	1	5	2		
	10.00	21.56	11.56	2	1	2	1	1	3.18	4	2	3
	4	2	3	1	1	3						
vidhya	147472c		29	2	3	3	2	2	3	2		
	12.00	16.20	6.20	2	2	2	2	1	3.98	4	2	3
	4	2	3	1	1	3						
parameswar	352340g		30	1	2	1	2	2	1	2		
	13.00	18.15	5.15	2	2	2	1	2	3.40	4	2	3
	4	2	3	1	1	3						
sandhiya	182304g		31	2	2	1	2	1	1	2		
	9.00	17.00	8.00	2	2	2	2	1	3.33	4	2	3
	4	2	3	1	1	3						

vanitha k	914475f		32	1	2	1	4	2	1	2	
5.00	8.15	3.15	2	2	2	1	2	3.33	4	2	3
4	2	3	1	1	3						
vandana m		417896g	33	2	1	3	2	2	1	1	
7.00	13.00	6.00	2	2	2	1	2	2.43	4	2	3
4	2	3	1	1	3						
asina	397535g		34	1	2	1	5	1	4	2	
12.30	25.30	0.00	2	2	1	3	2	3.10	3	2	3
4	2	2	1	1	3						
kavita d	274717g		35	2	2	1	5	2	4	2	
10.00	14.05	4.05	2	2	2	1	2	2.85	4	2	3
4	2	3	1	1	3						
renuka devi		165328g	36	1	2	1	2	2	1	2	
6.00	14.10	8.10	1	2	2	1	2	2.50	4	2	3
4	2	2	1	1	1						
saranya v		702160f	37	1	2	1	2	2	1	2	
7.00	13.00	6.00	2	2	2	1	2	2.83	4	2	3
4	2	3	1	1	3						
ezhilarasi	172083g		38	2	2	2	4	1	1	2	
12.00	18.30	8.30	2	2	2	2	2	3.29	4	2	3
5	2	2	1	1	3						
keertiga	417811g		39	2	2	1	2	1	1	2	
9.30	16.30	7.00	2	1	2	1	1	2.97	4	2	1
4	2	3	1	1	3						
anandhi sp		264515g	40	1	2	2	5	1	4	2	
12.00	24.00	0.00	2	2	2	3	2	3.24	3	2	3
4	2	3	1	1	3						
anusha	065092g		41	1	2	3	4	2	1	2	
8.00	13.30	5.30	1	2	2	2	2	3.74	4	2	3
4	2	3	1	1	1						
megala	993562f		42	2	2	3	2	2	1	2	
6.45	16.15	7.30	1	2	1	2	2	3.17	4	1	1
3	2	2	1	1	1						

sumati	107569g		43	2	2	3	4	1	1	2	
8.00	13.00	5.00	2	2	2	2	1	2.50	4	2	3
4	2	3	1	1	3						
vema joshna	379538g		44	1	2	3	4	2	1	2	
11.00	25.00	14.00	2	2	2	3	1	3.54	2	2	3
4	2	2	1	1	3						
mahmoola	198506g		45	2	1	1	2	1	1	2	
12.15	22.15	10.00	1	2	2	2	1	3.19	4	2	3
4	1	1	2	1	1						
selvi k	379005g		46	1	2	2	2	2	1	2	
10.00	14.00	4.00	2	2	2	3	2	2.40	1	2	3
4	1	2	2	1	3						
sunita	229164g		47	1	2	1	4	2	5	2	
12.00	24.00	0.00	2	2	2	3	2	3.36	3	2	3
4	2	2	1	1	3						
swapna	329646g		48	2	2	3	2	2	5	2	
5.30	10.00	4.30	2	2	2	2	2	2.61	4	2	3
4	2	3	1	1	3						
fathima	297572g		49	2	2	1	2	1	1	2	
12.00	18.25	6.25	2	1	2	1	2	2.91	4	2	3
4	2	3	1	1	3						
saritha	400833g		50	1	2	1	4	1	1	2	
8.00	20.30	0.00	2	2	1	3	1	3.38	3	2	3
4	2	3	1	1	3						
senthamil	253488d		51	2	3	1	4	1	3	2	
10.00	28.00	0.00	2	1	2	3	1	3.32	3	2	3
1	1	2	1	1	3						
vidivelli	165595g		52	1	2	1	2	2	1	2	
8.00	15.30	7.30	1	2	2	2	1	3.38	4	2	1
4	2	3	1	1	1						
nirmala d	132469b		53	2	2	1	2	1	1	2	
12.00	18.40	6.40	2	2	2	2	2	2.95	4	2	3
4	2	3	1	1	3						

punita g	235140g		54	1	2	1	4	1	1	2		
	13.00	16.00	3.00	1	2	2	3	1	3.98	1	2	3
	3	1	1	2	1	2						
uma r	174736g		55	1	2	1	2	1	2	2		
	13.00	19.35	6.35	2	2	2	2	1	3.18	4	1	3
	3	2	2	1	1	3						
lavanya m		165745g		56	2	2	1	2	2	1	1	
	11.14	17.38	6.24	2	2	1	2	1	3.00	4	2	3
	4	2	3	1	1	3						
sandhiya d		207940g		57	2	2	1	2	1	5	2	
	8.35	18.50	10.15	2	1	1	3	2	2.92	1	2	3
	4	2	3	1	1	3						
thejasvi	027655b		58	1	2	3	4	2	1	2		
	5.48	13.58	8.10	1	2	1	3	1	2.58	1	2	3
	4	2	3	1	1	1						
saranya s	179885g		59	2	1	1	1	1	1	2		
	11.18	18.23	7.05	2	2	2	1	1	2.20	4	2	3
	4	2	2	1	1	3						
manjula	187876g		60	1	2	1	5	1	2	2		
	12.30	24.30	12.00	2	2	1	3	1	3.56	2	2	1
	4	2	3	1	1	3						
madhuri		102079g		61	2	2	3	4	1	1	2	
	12.00	24.00	0.00	2	2	2	3	2	3.10	3	2	3
	1	2	2	1	1	3						
silpa	171691g		62	2	2	3	2	1	1	2		
	12.00	22.31	10.31	2	2	2	2	1	3.19	4	2	3
	4	2	3	1	1	3						
barani k	272375d		63	2	2	1	2	1	1	2		
	8.50	18.10	9.30	2	2	2	1	1	3.32	4	2	3
	4	2	3	1	1	3						
aiswarya		180072g		64	1	2	1	4	1	1	2	
	12.00	19.30	7.30	2	2	2	1	1	3.00	4	2	3
	4	2	3	1	1	3						

israth	109049g	65	2	2	2	2	1	1	2		
8.00	16.00	8.00	1	2	2	2	1	3.07	4	2	3
4	2	3	1	1	2						
sangeeta p	270871g	66	1	1	1	4	2	1	2		
6.00	10.30	4.30	1	2	2	1	1	2.87	4	2	3
4	2	3	1	1	1						
sandhya	420343g	67	1	2	1	2	1	1	2		
12.00	20.00	8.00	2	2	1	3	2	2.80	1	1	1
3	1	1	1	1	3						
sathyapriya	004225g	68	2	2	1	4	2	1	2		
10.35	17.45	7.10	2	2	2	1	1	3.60	4	2	3
4	2	3	1	1	3						
sangeeta	012033d	69	1	3	2	5	1	3	2		
12.00	20.00	8.00	2	2	2	3	1	2.78	2	2	3
4	2	3	1	1	3						
nithya	013496f	70	2	2	1	2	1	1	2		
10.00	18.00	6.00	2	2	2	3	1	3.56	2	2	3
4	2	3	1	1	3						
sangeeta d	028439g	71	2	2	1	2	1	1	2		
13.45	19.10	6.40	2	2	2	1	2	2.52	4	2	3
4	2	3	1	1	3						
ranatha	039222g	72	1	2	1	4	1	2	2		
6.40	16.50	10.10	2	2	1	3	2	3.28	2	2	2
3	2	2	1	1	3						
roseline	062137f	73	1	2	1	2	1	5	2		
11.35	17.18	5.43	2	1	2	1	1	3.80	4	2	3
4	2	3	1	1	3						
kavitha	227394g	74	2	2	1	4	1	1	2		
12.00	26.00	14.00	2	2	2	3	1	3.92	2	2	3
4	2	3	1	1	3						
kavita k	097120g	75	1	2	3	4	1	2	2		
8.45	20.10	11.35	2	2	1	3	1	2.32	3	2	3
4	2	3	1	1	3						

gomathy		099095f		76	2	2	1	2	1	1	2	
9.45	18.13	8.30	2	2	2	3	2	3.80	1	2	3	
4	2	3	1	1	3							
saranya m		104179g		77	1	2	1	2	2	1	2	
5.44	11.55	6.30	1	2	2	2	1	3.69	4	2	1	
4	2	3	1	1	2							
sasikala		107663f		78	2	2	3	4	2	1	2	
7.30	13.15	6.10	2	2	2	3	1	2.68	1	2	3	
4	2	3	1	1	3							
rajalakshmi		115308f		79	2	2	1	2	1	1	2	
8.00	14.55	6.55	2	1	2	1	2	2.93	4	2	3	
4	2	3	1	1	3							
priyadarshini		120297g		80	1	2	1	2	1	1	2	
9.30	17.15	7.45	2	2	2	1	2	3.70	4	2	3	
4	2	3	1	1	3							
sharmila		130565f		81	1	2	1	4	2	5	2	
8.43	13.55	5.05	1	2	1	3	2	3.54	1	2	3	
4	2	3	1	1	1							
nageswarama		198217g		82	2	2	3	2	1	1	2	
10.05	16.45	6.40	2	2	2	1	2	2.92	4	2	3	
4	2	3	1	1	3							
vandana		194687g		83	1	2	1	2	1	5	2	
8.00	17.45	0.00	2	1	2	3	2	3.60	3	2	3	
4	2	3	1	1	3							
narmadha m		131808b		84	2	2	1	2	2	1	1	
7.25	15.40	8.15	2	2	2	1	2	2.30	4	2	3	
4	1	2	1	1	3							
saranya		212348g		85	2	2	1	4	1	1	2	
12.30	23.00	10.30	2	2	2	3	1	3.00	2	2	3	
5	2	3	1	1	3							
asha s		190874g		86	1	1	3	2	1	1	2	
10.00	17.40	7.40	2	2	2	1	2	3.40	4	2	3	
4	2	3	1	1	3							

yagalaksmi		213532g		87	1	2	2	5	2	4	2
6.00	12.45	0.00	1	2	1	3	2	2.76	1	2	3
3	2	2	1	1	2						
malathy	188718g			88	2	2	1	2	1	1	2
10.10	15.50	5.40	2	2	2	2	1	3.07	4	2	3
4	2	3	1	1	3						
tasneem	199339g			89	1	2	1	2	2	1	2
10.15	16.40	0.00	2	2	2	3	2	3.28	3	2	3
4	2	3	1	1	3						
koteswari		198812g		90	2	2	1	2	1	1	2
12.30	20.15	7.45	2	2	2	2	2	2.95	4	2	3
4	2	3	1	1	3						
venu g	190476g			91	1	2	3	4	2	2	2
11.10	17.27	6.17	1	1	2	1	2	2.95	4	2	3
4	2	3	1	1	1						
hajira	285759g			92	2	2	2	2	1	1	2
11.45	15.43	4.58	2	2	2	1	2	2.83	4	2	3
4	2	3	1	1	3						
aysa	375741g			93	1	1	1	2	2	5	2
7.50	11.27	3.37	2	2	2	1	2	3.36	4	2	3
4	1	2	1	1	3						
saranya s	390454g			94	2	3	2	4	1	3	2
12.00	26.00	14.00	2	2	2	3	1	3.48	2	2	1
4	2	2	1	1	3						
lakshmipriya		300397f		95	2	2	2	2	1	5	2
12.00	17.35	0.00	2	2	2	3	2	3.62	1	2	3
4	2	3	1	1	3						
suganya	206537g			96	1	2	1	5	2	3	2
11.31	15.45	4.14	1	2	2	3	1	3.60	1	2	3
4	2	2	1	1	1						
varalaxmi		204726g		97	1	2	2	4	1	5	2
10.40	19.10	9.50	1	1	2	2	2	3.10	1	1	3
4	2	2	1	1	1						

sangeeta k		203450g		98	2	2	1	2	2	1	2	
8.50	13.45	4.50	2	2	2	1	1	2.84	4	2	3	
4	2	3	1	1	3							
lavanya m		203006g		99	1	2	1	4	2	1	2	
5.50	14.02	8.12	1	1	2	1	1	3.69	4	2	3	
4	2	3	1	1	1							
uma maheswari		295704g		100	2	2	3	4	2	1	2	
11.00	21.00	10.00	2	2	2	2	1	2.90	4	2	3	
4	2	3	1	1	3							
keertana j	249438g			101	2	1	1	2	1	5	2	
12.00	18.30	6.30	2	2	2	1	2	3.46	4	2	3	
4	2	3	1	1	3							
sangeeta	270881g			102	1	1	1	5	2	4	2	
7.45	13.03	5.58	2	2	2	1	1	2.87	4	2	3	
4	2	3	1	1	3							
monika k		387436g		103	2	1	3	4	1	5	2	
9.30	14.35	5.05	2	2	2	1	1	3.36	4	2	3	
4	2	3	1	1	3							
silambarasi		283063g		104	1	2	1	4	2	1	2	
6.30	12.45	6.15	1	2	2	2	1	2.80	4	2	3	
4	2	3	1	1	1							
shanmugpriya		199428g		105	1	2	2	1	2	5	2	
5.45	11.51	6.05	2	2	2	1	1	2.79	4	2	3	
4	2	3	1	1	3							
sangeeta k		203457g		106	2	3	1	4	1	1	2	
12.07	19.37	7.30	2	2	1	1	1	2.84	4	2	3	
4	2	3	1	1	3							
venda	225126g			107	1	2	1	2	1	1	2	
13.10	24.55	11.45	2	1	2	2	2	3.40	4	2	1	
4	2	3	1	1	3							
rekha r	326205g			108	2	2	1	2	1	1	2	
12.15	16.35	4.20	2	2	2	1	1	3.23	4	2	3	
4	2	3	1	1	3							

abirami	178102g		109	2	2	2	2	1	2	1	
12.00	24.00	12.00	2	2	2	2	1	2.50	4	2	3
4	2	3	1	1	3						
radhika a	067497g		110	1	3	1	4	1	2	2	
9.30	17.15	7.45	2	2	2	2	1	2.84	4	2	3
4	2	3	1	1	3						
imrana a	208345g		111	2	2	2	2	2	1	2	
8.40	12.50	4.10	2	2	2	2	1	3.59	4	2	3
4	2	3	1	1	3						
parimala devi	208133g		112	1	3	1	4	1	7	2	
11.15	17.15	6.00	1	2	2	2	1	3.34	4	2	3
4	2	3	1	1	2						
jayanthi v	178212g		113	1	2	2	4	2	2	2	
7.50	13.30	6.40	2	2	1	1	1	2.79	4	2	3
4	2	3	1	1	3						
parveen m	241155g		114	2	2	2	2	1	1	2	
12.00	19.10	7.10	2	2	2	1	2	3.10	4	2	3
4	1	3	1	1	3						
brinda	407968f		115	2	2	1	2	1	1	2	
10.40	22.00	12.00	2	2	2	2	2	3.24	4	2	3
4	2	3	1	1	3						
pramila c	260565g		116	1	2	3	5	2	3	2	
11.30	19.30	8.00	1	1	2	2	1	3.34	4	2	1
4	2	3	1	1	1						
saira	312078g		117	2	2	3	2	1	2	2	
12.00	19.00	7.00	2	2	2	2	2	3.70	4	2	2
4	2	3	1	1	3						
saranya s	208659g		118	1	2	2	4	2	1	2	
8.30	13.45	5.15	2	2	2	2	1	2.94	4	2	3
4	2	3	1	1	3						
santhiya	208831g		119	1	2	1	2	1	1	2	
10.15	17.30	7.15	1	2	2	1	2	2.63	4	2	3
4	1	2	1	1	1						

suganya	211222g		120	2	2	3	4	1	2	2	
12.00	16.00	0.00	2	2	2	3	1	2.00	3	1	1
3	1	2	1	1	3						
sandhiya s	212200g		121	1	2	1	2	2	1	2	
7.50	15.51	8.00	2	1	2	1	2	2.81	4	2	3
4	2	3	1	1	3						
malathi	211006g		122	2	2	2	5	1	4	2	
10.35	13.00	0.00	1	2	1	3	1	2.00	3	2	3
4	2	3	1	1	1						
dhanalakshmi d	210655g		123	1	2	1	2	2	1	2	
10.30	20.00	9.30	2	2	2	2	1	3.08	4	2	3
4	1	2	1	1	3						
sathya m	210590g		124	2	1	1	2	1	1	2	
10.00	17.14	7.14	2	2	2	2	2	3.00	4	2	3
4	2	3	1	1	3						
gowthami	210331g		125	1	2	1	4	1	1	2	
8.00	18.00	0.00	2	2	2	3	2	3.42	3	2	3
4	2	3	1	1	3						
vinitha	213511g		126	2	1	2	2	1	1	2	
10.32	16.45	6.15	2	2	2	1	2	2.84	4	2	3
4	2	3	1	1	3						
rekha r	212419g		127	2	1	1	5	1	3	2	
12.00	19.13	7.13	2	2	2	2	1	3.05	4	2	1
4	2	3	1	1	3						
sonia	213072g		128	1	1	1	4	2	1	2	
8.00	14.12	6.12	2	2	2	1	2	2.83	4	2	3
4	2	3	1	1	3						
saranya	212248g		129	2	2	1	4	1	1	2	
12.00	28.00	16.00	2	2	1	3	1	3.00	1	2	3
5	2	3	1	1	3						
rajeswari a	213538g		130	1	2	2	2	2	1	2	
10.00	17.17	7.17	1	2	2	1	2	3.07	4	2	3
4	2	3	1	1	1						

vidhyalakshmi		014334f		131	1	2	2	4	1	2	1	
10.00	16.43	6.43	2	2	2	1	2	2.80	4	2	3	
4	2	3	1	1	3							
kavyasree		014403g		132	2	2	3	2	1	1	2	
12.20	18.48	6.28	2	1	2	1	1	3.00	4	2	3	
4	2	3	1	1	3							
swetha v		061105d		133	1	2	2	4	1	1	2	
11.00	16.34	5.34	2	2	2	2	1	3.58	3	2	3	
5	2	3	1	1	3							
reshma		085445g		134	2	2	1	2	2	1	2	
12.00	16.11	4.11	2	2	2	2	2	3.02	4	2	3	
4	2	3	1	1	3							
jeyapriya s		089037d		135	1	2	1	4	2	1	2	
10.00	17.00	7.00	2	2	2	1	1	3.36	4	2	3	
4	2	3	1	1	3							
sasikala		121986g		136	2	3	1	5	1	3	1	
8.00	22.00	14.00	2	2	2	3	2	3.30	2	2	3	
4	2	3	1	1	3							
sasikala		123236g		137	1	2	2	2	1	2	2	
10.30	16.53	6.23	1	2	2	1	2	3.03	4	2	1	
4	2	3	1	1	1							
nikila		126520g		138	2	2	3	2	1	1	2	
11.30	18.22	6.44	2	2	2	2	2	3.11	4	2	3	
4	2	3	1	1	3							
bayis		140050g		139	2	1	1	5	1	3	2	
8.00	4.35	0.00	2	2	2	3	2	3.03	1	1	3	
4	1	2	1	1	3							
shenaz		151918g		140	1	2	2	2	1	1	2	
9.30	14.48	5.18	2	2	2	1	2	3.10	4	2	3	
4	2	3	1	1	3							
swmya		152800g		141	2	2	2	4	1	1	2	
12.00	20.13	8.00	2	2	2	1	1	3.30	4	2	3	
4	2	3	1	1	3							

nithya		163677g		142	1	2	2	2	1	2	2	
	11.30	17.47	7.17	2	2	2	2	1	3.22	4	2	3
	4	2	3	1	1	3						
ramalaksh		239767g		143	2	2	1	4	1	1	2	
	12.00	17.56	5.56	2	2	2	2	1	3.00	4	2	3
	4	2	3	1	1	3						
sathya g		167277g		144	1	2	2	2	1	1	2	
	9.30	15.45	6.15	1	2	1	2	1	3.12	4	2	1
	4	2	3	1	1	2						
uma		172334g		145	1	2	1	4	2	2	1	
	11.00	17.30	6.30	2	2	2	2	1	2.68	4	2	2
	4	2	3	1	1	3						
induja		174624g		146	2	2	1	5	2	3	2	
	11.03	18.43	7.40	1	2	2	2	2	3.56	4	2	3
	4	2	3	1	1	1						
priya		175017g		147	2	3	1	2	1	1	2	
	12.00	28.00	16.00	2	2	2	3	1	1.00	3	1	3
	4	2	2	1	1	3						
iswar		175076g		148	1	2	1	5	2	3	2	
	11.00	18.34	7.34	2	1	2	2	2	3.10	4	2	3
	4	2	3	1	1	3						
aishya i		176511f		149	2	2	1	2	1	1	2	
	10.40	16.50	6.10	2	2	2	1	1	3.12	4	2	3
	4	2	3	1	1	3						
shajida		184719g		150	1	2	1	4	1	1	2	
	12.00	16.50	4.50	2	2	2	1	1	3.48	4	2	3
	4	2	3	1	1	3						
vaishna		185741g		151	1	2	1	2	2	1	2	
	10.40	15.57	5.10	2	2	2	2	1	2.99	4	2	3
	4	2	3	1	1	3						
divya		176882g		152	2	2	1	4	1	1	2	
	12.00	20.00	0.00	1	2	2	3	2	3.48	1	2	3
	6	2	3	1	1	1						

rajeswari	182232g		153	2	2	1	2	1	1	2		
12.004	17.572	5.573	2	1	1	1	2	2.80	4	2	3	
			1	1	3							
geeta	181859g		154	1	2	2	4	1	1	2		
10.154	17.452	7.303	2	2	2	1	2	2.80	4	2	3	
			1	1	3							
ameena	180953g		155	1	2	1	2	1	1	2		
12.004	22.002	10.003	2	2	2	2	1	3.24	4	2	3	
			1	1	3							
komathi	179680g		156	2	2	1	4	1	1	2		
12.004	21.512	9.513	2	2	1	1	1	3.64	4	2	3	
			1	1	3							
jyoti	179282f		157	1	2	3	2	1	1	2		
11.004	19.232	8.232	2	2	2	2	1	2.83	4	2	1	
			1	1	3							
pavitra	178642g		158	2	2	3	5	2	3	1		
8.404	14.502	6.103	2	2	2	1	1	2.93	4	2	3	
			1	1	3							
geeta	201044g		159	2	2	1	4	1	1	2		
9.504	23.151	0.002	2	1	2	3	1	2.68	3	1	3	
			1	1	3							
jyoti	192719g		160	1	2	1	2	1	5	2		
12.003	20.002	0.001	1	2	1	3	1	2.54	1	2	3	
			1	1	1							
banupriya	194871g		161	2	2	1	4	1	2	2		
10.004	15.412	5.003	2	2	2	3	2	2.86	1	2	3	
			1	1	3							
saranya	195973g		162	1	2	1	2	1	5	2		
12.004	24.002	0.003	2	2	2	3	2	2.68	3	2	3	
			1	1	3							
mythili	197101g		163	1	2	3	2	1	2	2		
9.004	16.332	7.333	2	2	2	1	2	2.45	4	2	3	
			1	1	3							

kaplana	197112g		164	2	2	3	4	1	2	2		
	12.00	18.27	6.27	2	2	2	2	1	3.40	4	2	1
	4	2	3	1	1	3						
jayachitra	197278g		165	2	2	2	2	1	1	2		
	10.30	20.47	10.17	2	2	2	2	2	2.70	4	2	3
	4	2	3	1	1	3						
devi	197417g		166	1	1	1	5	1	1	2		
	13.00	21.24	8.24	2	1	2	1	2	3.26	4	2	3
	4	2	3	1	1	3						
raheela	198045g		167	2	2	1	2	2	5	2		
	12.00	21.43	9.43	2	2	2	3	2	3.12	1	2	3
	4	2	3	1	1	3						
triveni	199763g		168	1	2	3	2	1	2	2		
	12.00	23.56	11.56	2	2	2	1	1	2.90	4	2	3
	4	2	3	1	1	3						
kavita	202985g		169	1	2	1	4	1	1	2		
	13.00	22.11	9.11	1	2	2	1	1	3.37	4	2	3
	4	2	3	1	1	1						
usha	200024g		170	2	3	1	4	1	2	2		
	11.30	20.55	9.25	2	2	2	2	1	3.26	4	2	3
	4	2	3	1	1	3						
anitha	404573g		171	2	2	3	2	1	1	2		
	12.00	22.46	10.46	2	1	2	1	2	2.88	4	2	3
	4	2	3	1	1	3						
nisa rh	417178g		172	1	2	2	2	1	1	2		
	10.00	17.10	7.10	2	2	2	1	1	3.45	4	2	1
	4	2	3	1	1	3						
deepa l	325700g		173	2	2	2	4	2	2	2		
	9.45	17.03	6.17	2	2	2	1	2	3.04	4	2	3
	4	2	3	1	1	3						
saranya	336331g		174	1	2	1	2	1	1	2		
	12.00	23.55	11.55	2	2	2	1	2	3.05	4	2	3
	4	2	3	1	1	3						

janani m	380600g		175	2	2	2	5	1	3	2	
13.00	25.17	12.17	2	2	2	3	2	2.86	1	2	3
4	2	3	1	1	3						
tejovathy	412418g		176	1	2	3	2	2	1	2	
12.00	22.58	10.58	2	2	2	1	2	2.78	4	2	3
4	2	3	1	1	3						
nandini g	375513g		177	1	2	2	1	2	5	2	
10.30	18.32	8.02	2	2	2	1	2	2.86	4	2	3
4	2	3	1	1	3						
madhavi g	407095g		178	2	2	3	4	1	2	2	
12.00	18.34	0.00	2	2	2	3	1	3.36	1	1	3
3	2	2	1	1	3						
suganya	381020g		179	1	2	1	4	1	2	2	
10.45	20.21	10.21	1	2	2	1	2	2.93	4	2	3
4	2	3	1	1	1						
rajati	331089g		180	2	2	2	4	2	2	2	
12.00	23.40	11.40	2	2	2	1	1	3.01	4	2	3
4	2	3	1	1	3						
devi r	291681g		181	1	2	1	2	2	1	2	
12.00	22.34	10.34	2	2	2	1	2	2.78	4	2	3
5	2	3	1	1	3						
valarmathy	277025g		182	2	1	1	2	1	1	2	
12.00	21.03	9.03	2	2	2	1	2	3.44	4	2	3
4	2	3	1	1	3						
kanimozhi	366955g		183	1	2	1	2	1	1	2	
10.00	19.50	9.50	2	2	2	1	1	3.20	4	2	3
4	2	3	1	1	3						
sivasakti	299775g		184	2	2	1	4	1	1	2	
13.00	20.47	7.47	2	2	2	1	2	3.29	4	2	3
5	2	3	1	1	3						
hina f	411664g		185	2	1	2	2	1	5	2	
12.00	18.49	8.49	2	2	1	3	1	3.26	1	2	3
4	2	3	1	1	3						

anitha k	325221g		186	1	2	1	2	2	1	2		
7.30	17.07	9.37	2	2	2	1	2	3.40	4	2	3	
4	2	3	1	1	3							
saraswati d	427970g		187	1	3	2	4	2	3	2		
10.00	16.04	6.04	2	2	2	1	1	3.17	4	2	3	
4	2	3	1	1	3							
sheela	355023g		188	2	2	3	2	1	5	2		
12.00	21.39	9.39	2	2	2	1	1	3.10	4	2	3	
4	2	3	1	1	3							
keerthiga	408354g		189	2	2	2	4	2	1	2		
13.00	21.23	8.23	2	2	2	2	2	2.75	4	2	3	
4	2	3	1	1	3							
devi s	308025g		190	1	2	1	5	2	4	2		
12.00	25.40	11.42	2	2	2	2	2	2.41	4	2	3	
4	1	2	1	1	3							
nouhira	288575g		191	1	2	3	2	1	1	2		
10.30	21.10	10.20	1	2	2	2	1	3.54	4	2	3	
4	2	3	1	1	2							
sujatha	996561f		192	2	2	1	2	2	1	2		
7.00	15.29	8.29	2	2	2	1	1	2.66	4	2	3	
4	2	3	1	1	3							
sinesa	369445g		193	2	2	3	4	1	1	2		
12.00	22.52	10.52	2	2	2	1	2	3.13	4	2	3	
4	2	3	1	1	3							
monisha r	321927g		194	1	1	2	2	2	1	2		
10.00	20.03	10.03	2	2	2	1	2	2.92	4	2	3	
4	2	3	1	1	3							
keerthana d	369998g		195	1	2	3	4	1	5	2		
8.00	23.43	15.43	2	1	2	3	2	3.82	2	2	3	
1	2	3	1	1	3							
jhanvi	295338g		196	2	2	3	2	1	1	2		
12.00	18.02	8.02	2	2	2	1	2	3.01	4	2	3	
4	2	3	1	1	3							

thabassum		241598g		197	1	2	1	2	2	2	2
	10.00	21.42	11.42	2	2	2	1	2	3.10	4	2	3
	4	2	3	1	1	3						
anjalai		402207g		198	2	3	3	4	1	3	2	
	12.00	19.48	7.48	2	2	2	1	2	3.08	4	2	3
	4	2	3	1	1	3						
divya v		378643g		199	2	2	2	2	1	1	2	
	12.00	26.39	14.39	2	2	2	2	2	3.62	4	2	1
	5	2	3	1	1	3						
dhivya		430172f		200	1	2	1	4	1	1	2	
	10.00	20.39	10.39	1	2	1	1	2	3.48	4	2	3
	4	2	3	1	1	1						
sujatha		433386g		201	2	2	1	2	1	1	2	
	11.00	25.00	6.00	2	2	2	3	1	3.26	3	2	3
	4	2	3	1	1	3						
hemavathi		390805g		202	1	1	3	2	1	1	2	
	12.00	23.10	11.10	2	2	2	2	1	3.40	4	2	3
	4	2	3	1	1	3						
meghala		340253g		203	1	2	1	4	2	1	2	
	10.00	22.00	0.00	1	2	2	3	2	3.10	3	2	3
	1	2	3	1	1	2						
shermila		332445g		204	2	2	1	2	1	1	2	
	12.00	22.30	10.30	2	2	2	2	1	3.68	4	2	3
	4	2	3	1	1	3						
monika		396921g		205	2	2	1	2	1	1	2	
	11.30	25.30	14.00	2	2	2	2	2	3.10	4	2	3
	4	2	3	1	1	3						
vinothini		467021f		206	1	2	1	4	1	1	2	
	12.00	20.50	8.50	2	2	2	2	2	3.10	4	2	3
	4	2	3	1	1	3						
banu		356547g		207	1	2	1	4	1	1	2	
	10.00	17.17	7.17	2	2	2	1	2	2.73	4	2	3
	4	2	3	1	1	3						

divya		299631g		208	2	2	1	5	1	3	2	
	10.00	19.43	9.43	2	2	2	1	2	2.78	4	2	3
	4	2	3	1	1	3						
rekha		338387g		209	1	2	2	2	1	2	2	
	10.00	17.50	7.50	2	2	2	1	2	2.62	4	2	3
	4	2	3	1	1	3						
padmapriya		317305f		210	2	2	1	4	1	1	2	
	12.00	25.00	13.00	2	2	2	1	1	3.30	4	2	3
	5	2	2	1	1	3						
chetana		511142f		211	2	2	2	2	1	1	2	
	12.00	19.45	7.45	2	2	2	3	1	2.94	4	2	3
	4	2	3	1	1	3						
priyanka b		516340f		212	1	2	3	4	1	1	2	
	11.00	19.00	8.00	2	2	2	1	2	2.79	4	2	3
	4	2	3	1	1	3						
yasmin		288215g		213	2	2	2	2	2	1	2	
	12.00	25.33	13.33	2	2	2	2	1	3.03	4	2	3
	1	2	3	1	1	3						
punitavalli		339933g		214	1	2	2	4	1	1	2	
	11.30	23.40	12.40	2	2	2	3	2	3.84	2	2	3
	4	2	3	1	1	3						
prema s		352169g		215	1	2	1	2	1	2	2	
	12.00	20.20	8.20	2	2	2	2	2	3.00	4	2	3
	4	2	2	1	1	3						
salma		387310g		216	2	2	1	4	2	5	2	
	10.00	16.50	6.50	2	2	2	2	1	3.40	4	2	3
	4	2	3	1	1	3						
shalini b		278536g		217	2	2	1	2	1	1	2	
	12.00	26.00	0.00	2	2	2	3	1	3.70	4	2	3
	4	2	3	1	1	3						
bhuvaneswari		993572f		218	1	2	2	4	1	1	2	
	12.00	19.20	7.20	2	2	2	1	1	3.52	4	2	3
	4	2	3	1	1	3						

induja		863294c		219	2	2	1	2	1	1	2	
	10.00	18.46	8.46	2	2	2	1	1	3.41	4	2	3
	4	2	3	1	1	3						
selvi k		379006g		220	1	2	1	2	1	1	2	
	12.00	17.30	0.00	1	2	2	3	2	2.40	1	2	3
	4	2	3	1	1	2						
saritha		400843g		221	1	2	1	4	1	1	2	
	12.00	24.00	0.00	2	2	2	3	2	3.38	3	2	3
	4	2	3	1	1	3						
jeyalaxmi		318580g		222	2	2	2	5	1	3	2	
	12.00	17.59	5.59	2	2	2	2	2	2.85	4	2	3
	4	2	3	1	1	3						
prema		399092g		223	2	2	2	2	1	2	2	
	12.00	18.58	6.58	2	2	2	1	1	2.57	4	2	3
	4	2	3	1	1	3						
sharmila r		412862g		224	1	2	2	2	1	1	2	
	12.00	18.33	6.33	2	2	2	2	1	3.20	4	2	3
	4	2	3	1	1	3						
amudha		996575f		225	2	2	1	2	1	1	2	
	9.40	18.02	8.22	2	2	2	2	1	2.95	4	2	3
	4	2	3	1	1	3						
bhagyavathy c		338583g		226	1	2	1	5	2	3	2	
	12.00	18.00	0.00	1	2	1	3	1	2.72	1	2	3
	5	2	3	1	1	1						
bhagavati		295003g		227	2	3	1	2	1	1	2	
	12.00	17.43	0.00	1	2	2	3	1	2.84	1	2	3
	4	2	3	1	1	1						
rajalaxmi		107519g		228	1	2	1	4	1	1	2	
	10.00	15.14	5.14	2	2	2	3	2	2.70	1	2	3
	4	2	3	1	1	3						
vanitha		435580g		229	1	2	2	4	1	1	2	
	12.00	19.20	7.20	1	2	1	3	2	2.66	1	2	3
	4	2	3	1	1	1						

fatima	275191g		230	2	2	1	2	1	5	2	
12.00	20.54	8.54	2	2	2	1	1	3.26	4	2	3
4	2	3	1	1	3						
gajalakshmi	404598g		231	2	2	1	2	1	1	2	
13.00	25.00	12.00	2	2	2	1	2	3.09	4	2	3
4	2	3	1	1	3						
sumangali	430445g		232	1	2	2	2	2	1	2	
11.30	21.25	0.00	1	2	2	3	2	3.30	3	2	3
4	2	3	1	1	1						
lavanya	274608g		233	1	2	2	5	1	3	2	
12.00	22.57	10.57	2	2	2	1	2	3.02	4	1	3
1	2	1	1	1	3						
roja m	418934g		234	2	2	2	2	1	1	2	
10.30	19.26	8.56	2	2	2	1	2	2.57	4	2	3
4	2	3	1	1	3						
radhika	996557f		235	2	2	2	4	2	1	2	
12.30	22.42	10.12	2	2	2	2	1	2.75	4	2	3
4	2	3	1	1	3						
hemavathy	295047g		236	1	1	1	2	1	5	2	
10.00	19.32	9.32	2	1	2	1	2	3.04	4	2	3
4	2	3	1	1	3						
kavitha	996588f		237	2	2	1	4	1	1	2	
8.00	13.48	0.00	1	2	2	3	1	2.72	1	1	3
4	2	2	1	1	1						
vani a	364953g		238	1	2	1	5	1	3	2	
12.00	23.35	11.35	2	2	2	2	1	2.67	4	2	3
4	2	3	1	1	3						
sujita	969823b		239	1	2	3	4	2	2	2	
11.00	21.45	10.45	2	2	2	1	2	3.07	4	2	3
4	2	3	1	1	3						
kalpana r	428458g		240	2	2	2	4	1	1	2	
13.00	24.34	11.34	2	2	2	1	2	2.87	4	2	3
4	2	3	1	1	3						

pavitra	286006g		241	1	2	1	2	2	1	2		
	12.00	20.53	8.53	1	2	1	1	2	2.94	4	2	3
	4	2	3	1	1	1						
saranya	302375g		242	2	2	2	4	1	1	2		
	12.00	25.50	13.50	2	2	2	2	1	3.57	4	2	3
	4	2	3	1	1	3						
anjali	390897g		243	1	1	3	1	1	5	1		
	8.45	19.55	11.10	2	2	2	1	1	2.71	4	2	3
	4	2	3	1	1	3						
chandralekha	350508g		244	2	2	3	2	1	5	2		
	13.00	23.51	10.51	2	2	2	2	1	3.10	4	2	3
	4	2	3	1	1	3						
hajira	315233g		245	1	2	1	4	2	5	2		
	10.00	21.20	11.20	1	2	2	1	2	3.30	4	1	3
	3	2	2	1	1	1						
renuka devi	815680f		246	2	2	1	2	1	5	2		
	12.00	24.34	12.34	2	1	2	1	2	3.33	4	2	3
	1	1	1	1	1	3						
deepika	297160g		247	2	2	2	2	1	5	2		
	10.00	23.30	13.30	1	2	1	2	2	3.34	4	2	3
	4	2	3	1	1	2						
pavitra	109035g		248	1	2	2	4	2	1	2		
	11.00	23.00	0.00	2	2	2	3	2	3.56	3	1	1
	1	2	2	1	1	3						
suganya	109037g		249	2	2	2	2	1	1	2		
	12.00	19.41	7.41	2	2	2	1	1	3.61	4	2	3
	4	2	3	1	1	3						
prabhavathy	377747g		250	1	2	1	2	1	7	2		
	9.40	16.52	7.12	2	2	2	1	2	3.11	4	2	3
	4	2	3	1	1	3						
barkhat	109044g		251	2	2	1	2	1	1	2		
	12.00	21.27	9.27	2	2	2	2	2	2.95	4	2	3
	4	2	3	1	1	3						

megala		378267g		252	1	2	2	2	1	5	2	
	12.004	18.122	6.123	2	2	2	1	1	3.23	4	2	3
satya		334569g		253	1	1	1	4	2	1	2	
	8.401	16.571	8.171	1	2	1	2	1	2.71	4	2	3
sudiya		333479g		254	2	2	1	5	1	3	2	
	12.001	18.322	6.322	2	2	2	1	2	3.13	4	2	3
priyanka		392133g		255	1	2	1	4	1	1	2	
	11.454	18.562	7.113	1	2	2	1	1	3.10	4	2	3
priya		467803g		256	2	2	2	2	1	5	2	
	12.004	21.402	9.403	2	1	2	2	1	3.35	4	2	1
vaishnavi		417410g		257	1	2	2	2	2	5	2	
	12.004	18.242	6.243	2	2	2	1	1	3.43	4	2	3
shamala		437343g		258	2	2	3	2	1	1	2	
	10.004	15.502	5.513	2	2	2	2	2	3.00	4	2	2
priya s		320365g		259	2	2	1	4	1	1	2	
	12.004	21.502	9.503	2	2	2	2	1	3.30	4	2	1
gunasundari		439621g		260	1	2	1	2	1	1	2	
	10.404	20.502	10.103	2	2	2	2	2	3.13	4	2	3
ammu		061546G		261	1	2	1	2	1	1	2	
	12.004	22.412	10.413	2	2	2	2	1	3.22	4	2	3
shoba		132594c		262	2	2	1	4	1	5	2	
	12.004	22.312	10.313	2	2	2	2	2	3.21	4	2	3

suganya	245780g		263	1	2	1	2	2	5	2		
	10.30	15.40	5.20	2	2	2	1	1	3.59	4	2	3
	4	2	3	1	1	3						
jessi	266077g		264	2	2	1	2	1	1	2		
	12.00	26.17	14.17	2	2	2	2	1	3.07	4	2	3
	4	2	3	1	1	3						
sasikala	288130g		265	1	2	3	1	1	1	2		
	11.00	14.50	4.50	1	2	1	3	2	3.10	1	2	3
	3	2	3	1	1	1						
meenakshi	289751g		266	2	2	3	2	1	1	2		
	10.00	22.43	12.43	2	2	2	2	1	3.13	4	2	3
	4	2	3	1	1	3						
durgadevi	329619g		267	1	2	1	2	2	1	2		
	9.00	16.38	7.38	2	2	2	1	2	2.90	4	2	3
	4	2	3	1	1	3						
jayalakshmi	330534g		268	2	3	2	4	1	3	1		
	12.00	21.10	9.10	2	2	2	3	1	2.40	1	2	3
	4	2	3	1	1	3						
sugashini	342185g		269	1	2	1	2	2	1	2		
	12.00	23.08	11.08	2	2	2	1	2	3.08	4	2	3
	4	2	3	1	1	3						
shakira	344759g		270	1	2	1	2	1	2	2		
	10.00	22.29	12.29	2	2	2	1	1	3.00	4	2	3
	4	2	3	1	1	3						
anjaly	737689d		271	1	2	1	2	2	1	2		
	8.00	16.30	8.30	2	1	2	2	1	3.10	4	2	3
	4	2	3	1	1	3						
jeeva	507029g		272	2	2	1	2	1	1	2		
	6.00	11.49	5.49	1	2	1	3	1	3.08	1	2	3
	4	2	3	1	1	1						
prameela	363638g		273	2	2	3	2	1	1	2		
	12.00	19.25	7.25	2	2	2	1	1	3.41	4	2	3
	4	2	3	1	1	3						

naziya		393984g		274	1	2	1	4	1	5	2	
	6.00	18.00	12.00	2	2	2	3	1	3.32	1	2	3
	4	2	3	1	1	3						
lavanya		364356g		275	2	2	3	1	1	2	2	
	12.00	20.36	8.36	2	2	2	1	1	2.48	4	2	3
	4	2	3	1	1	3						
rithu		365552g		276	1	2	2	2	2	1	2	
	8.00	19.43	11.43	2	2	2	1	2	3.34	4	2	3
	4	2	3	1	1	3						
yasmeen			367117g	277	2	2	1	2	2	5	2	
	10.30	16.41	6.11	2	2	2	3	2	3.80	1	2	3
	4	2	3	1	1	3						
chitra		367653g		278	1	2	2	4	1	1	2	
	7.00	16.16	9.16	2	2	2	1	2	3.10	4	2	3
	4	2	3	1	1	3						
akila		369406g		279	2	2	2	2	2	1	2	
	8.00	15.44	7.44	2	2	2	3	2	2.98	1	2	3
	4	2	3	1	1	3						
ramya		370487g		280	1	2	1	2	1	1	2	
	9.40	17.35	8.35	2	2	2	3	2	2.66	1	2	3
	4	2	3	1	1	3						
anu		706629d		281	2	3	1	4	1	2	2	
	12.00	19.29	7.29	1	2	2	2	2	2.89	4	2	3
	4	2	3	1	1	3						
divya		347409g		282	1	2	3	4	1	1	2	
	11.00	18.03	7.03	2	2	2	1	2	2.78	4	2	3
	4	2	3	1	1	3						
sakthivani			348231g	283	2	2	1	2	1	1	2	
	9.45	15.56	6.11	2	2	2	1	2	3.26	4	2	3
	4	2	3	1	1	3						
mohana			349530g	284	1	2	1	4	2	1	2	
	8.00	13.00	5.00	2	2	2	2	2	3.11	4	2	3
	4	2	3	1	1	3						

chandramma	355790g	285	2	2	2	2	1	1	2		
12.00	20.33	8.33	2	2	1	3	2	3.50	2	2	3
3	2	3	1	1	3						
reddy	380928g	286	2	1	3	2	1	5	2		
12.00	24.30	12.30	2	2	2	3	1	2.98	2	1	1
4	2	3	1	1	3						
kalpana	354308g	287	2	2	1	2	2	1	2		
10.00	15.40	5.40	2	2	2	1	1	3.68	4	2	3
4	2	3	1	1	3						
sumiya	352667g	288	1	2	1	2	2	1	2		
12.00	18.59	6.59	2	2	2	2	1	2.93	4	2	3
4	2	3	1	1	3						
bharatipriya	469310g	289	2	2	1	4	1	1	2		
12.00	20.45	8.45	2	2	2	1	2	3.60	4	2	3
4	2	3	1	1	3						
mandeela	507902g	290	1	3	3	4	1	1	2		
11.30	21.51	10.21	2	2	2	2	2	2.63	4	2	2
4	2	3	1	1	3						
pushpanjali	468583g	291	2	2	1	2	2	1	2		
12.00	22.42	10.42	2	2	2	1	2	3.63	4	2	1
1	2	2	1	1	3						
prateeba	457734g	292	1	2	1	4	1	1	2		
10.00	16.11	6.11	2	2	2	1	1	2.92	4	2	3
4	2	3	1	1	3						
maseeha	395319g	293	1	2	2	4	1	2	2		
12.00	19.13	7.13	2	2	2	1	1	3.15	4	2	3
4	2	3	1	1	3						
rubina j	507934g	294	2	2	1	2	1	1	2		
10.00	14.00	4.00	2	2	2	3	2	2.50	1	2	3
4	2	3	1	1	3						
bhuvaneswari	493017g	295	2	2	1	2	2	1	2		
12.00	24.24	12.24	2	2	2	1	2	3.48	4	2	3
4	2	3	1	1	3						

susmitha		241023g		296	1	2	3	4	1	1	2
	13.00	23.40	10.40	2	2	2	2	2	2.85	4	2	3
	4	2	3	1	1	3						
shobha		132594C		297	1	2	1	2	2	1	2	
	11.00	21.31	10.31	2	2	2	1	2	3.21	4	2	3
	4	2	3	1	1	3						
fatima		975782f		298	1	1	2	2	2	1	2	
	10.00	15.03	5.03	2	2	2	1	2	3.34	4	2	3
	4	2	3	1	1	3						
amreen		507972g		299	2	2	1	2	1	1	2	
	12.00	22.00	10.00	2	2	2	1	2	2.40	4	2	3
	4	2	3	1	1	3						
almas		380244g		300	1	2	2	2	1	5	2	
	10.00	21.30	11.30	2	2	2	2	2	3.01	4	2	3
	4	2	3	1	1	3						